

EPA Reg. Jacket 91300-5



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 4, 2018

Ann M. Tillman
Agent for Promika, LLC
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig harbor, WA 98332

Subject: Label Amendment – Modification of CRP packages
Product Name: PROMIKA ZOGUARD PLUS FOR DOGS
EPA Registration Number: 91300-5
Application Date: 4-Aug-2017
Decision Number: 532222

Dear Ms. Tillman,

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at Breedon-Alemi.Julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

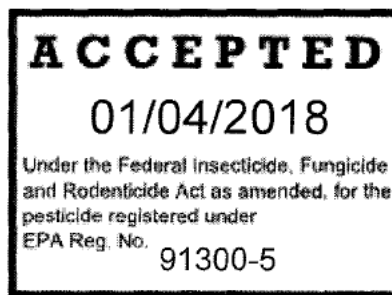
Primary brand name: Promika ZoGuard Plus for Dogs

Alternate Brand Name: Fortress Defense for Dogs

Heritage Plus for Dogs

Sublabel 1: Promika ZoGuard Plus for Dogs {Two alternate child resistant package types are included: the current approved CPR is described as an applicator inside a CRP blister and sold as a 3-count (strip of 3 applicators). The alternate CRP being added is described as a CRP blister applicator and is supplied as a 3 count and a 4 count or as multiples of 3- and 4- counts.}

Sublabel 2: Promika ZoGuard Plus for Dogs {single applicator. This alternate CRP is described as a CRP blister applicator and is supplied as a single applicator (1-count) in a foil pouch.}



Sublabel 1: Promika ZoGuard Plus for Dogs

[text in [] denotes optional language]

{text in {} denotes location of text on packaging, notes to reviewer, text that will not be on final label}

(text in () appears on label)

{Front Panel of Carton}

Promika ZoGuard Plus for Dogs

[Alternate brand name: Fortress Defense for Dogs; Heritage Plus for Dogs]

{The word “Dogs” in the product name will be 75% of the height of the largest letter in the primary brand name.}

{Large clear picture of dog in appropriate breed/weight class on front panel to be included}

{One of the following statements will appear on the front panel.}

For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR}
For use ONLY on dogs and puppies 5[-] [to] 22 lbs and 8 weeks or older {OR}
For use ONLY on dogs & puppies 5[-] [to] 22 lbs and 8 weeks or older {OR}
ONLY For Dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR}
ONLY For Dogs & Puppies 8 weeks or older and 5[-] [to] 22 lbs {OR}
ONLY For Dogs & Puppies 8 weeks or older & 5[-] [to] 22 lbs

{Optional Marketing Claim}

[[3][6][12] Month Supply]

[4][8][12] Month Supply

{When used, all three optional statements below will appear together on the same panel.}

[Contains Fipronil and (S)-Methoprene, the active ingredients used in FRONTLINE® Plus for Dogs]

[Frontline is a registered trademark of Merial]

[(Brand Name) is not manufactured or distributed by Merial, seller of Frontline® Plus for Dogs]

{See optional graphics on pages 13-14 of this label that may or may not appear on front panel of carton}

ACTIVE INGREDIENTS:

Fipronil..... 9.80%
(S)-Methoprene..... 8.80%

OTHER INGREDIENTS: 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements and First Aid

See Side Panel for Storage and Disposal

See inside panels and insert for additional Directions for Use

Net Contents: X fl. oz. [(mL)]

[3][Three][6][Six][12][Twelve] [Applicators each containing]

[0.023 fl oz (0.67 mL)]

[0.045 fl oz (1.34 mL)]

[0.091 fl oz (2.68 mL)]

[0.136 fl oz (4.02 mL)]

[4][Four] [8][Eight] [12][Twelve] [Applicators each containing]

[0.023 fl oz (0.67 mL)]
[0.045 fl oz (1.34 mL)]
[0.091 fl oz (2.68 mL)]
[0.136 fl oz (4.02 mL)]
[3][6][12] Applications
[4][8][12] Applications



{a 1.5cm x 1.5cm cat prohibition icon in a box located at the lower right hand corner of the front panel in yellow
with black images}

{End Front Panel of Carton}

{BACK PANEL OF CARTON}

Promika ZoGuard Plus for Dogs

[In Case of Emergency, call: XXX-XXX-XXXX] [Non-Emergency, call XXX-XXX-XXXX] [Formulated in USA]

[Manufactured For][Distributed By]:

[Promika, LLC.
5000 CentreGreen Way, Suite 100
Cary, NC 27513]

EPA Reg. No. 91300-5
EPA Est. No. XXXX-XXX-XXX

READ ENTIRE LABEL BEFORE EACH USE.

{One of these statements will be used}

[For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older
{OR} For use ONLY on dogs and puppies 5[-] [to] 22 lbs and 8 weeks or older
{OR} For use ONLY on dogs & puppies 5[-] [to] 22 lbs and 8 weeks or older
{OR} ONLY For Dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older
{OR} ONLY For Dogs & Puppies 8 weeks or older and 5[-] [to] 22 lbs
{OR} ONLY For Dogs & Puppies 8 weeks or older & 5[-] [to] 22 lbs]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product. This product is not a substitute for prescribed Heartworm preventative.

FIRST AID	
If in eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
If swallowed	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If on skin	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, you may contact SafetyCall at 1-844-685-9173 seven days a week, 24-hours a day.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY

STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs.

How to open:

Refer to package insert for directions on how to open package.

How to apply:

Remove product applicator from the package. Separate one applicator from the others. Hold the applicator with notched end pointing up and away from the face and body.

[Snap the outline of the tip back to allow access to the [dotted tip of the] applicator]]. {OR}

[Snap the applicator tip [backwards] [across the marked line] [to allow access to the] [dotted tip] [notches]].

{OR} [Holding the applicator away from your and your dog's eyes, snap the applicator tip [at notched line] to open.] Invert applicators over dog and use open end to part dog's hair. Squeeze applicator firmly to apply all of the solution to a single spot on the dog's skin, as directed below. Do not apply more often than once every [30 days][4 weeks][month].

{For cartons containing 0.67 mL (0.023 fl oz) applicators}

Only For Dogs Weighing 5 [-] [to] 22 lbs. & 8 weeks and older. Do not apply to dogs or puppies weighing less than 5 lbs.

Apply one applicator (0.67 mL)(0.023 fl oz)

[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 1.34 mL (0.045 fl oz) applicators}

Only For Dogs Weighing 23 [-] [to] 44 lbs. & 8 weeks and older.

Apply one applicator (1.34 mL)(0.045 fl oz)

[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 2.68 mL (0.091 fl oz) applicators}

Only For Dogs Weighing 45 [-] [to] 88 lbs. & 8 weeks and older.

Apply one applicator (2.68 mL)(0.091 fl oz)

[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 4.02 mL (0.136 fl oz) applicators}

Only For Dogs Weighing 89 [-] [to] 132 lbs. & 8 weeks and older. Do not use more than one applicator per treatment for one dog regardless of the dog's weight.

Apply one applicator (4.02 mL)(0.136 fl oz)

[as a spot [on] [to] the dog's back between the shoulder blades.]

PRODUCT INFORMATION

Use [Brand Name] [this product] monthly for control of fleas, ticks, [and] chewing lice, [and] mosquitos].

[Studies show that] [Brand Name] [this product] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Avoid contact with treated area until dry. Do not reapply for [30 days] [4 weeks][1 month].

{The following Side Effects text in a box will be placed in the lower right hand corner of back panel immediately above the cat warning box.}

Side Effects (Dogs): Monitor your dog after application. Some dogs may experience temporary startle effects when any product is applied. Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. In some cases gastrointestinal signs such as vomiting and diarrhea may occur. If these or other side effects occur, consult your veterinarian or call SafetyCall at 1-844-685-9173. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application.

{a 1.5 cm x 1.5 cm cat prohibition icon and warning text in a box, black on yellow background, will be placed on the lower right hand corner of back panel.}



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

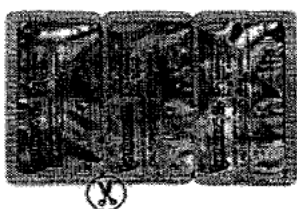
{END BACK PANEL OF CARTON}

{Begin Package Insert for applicator inside the CRP blister (3-Count)}

How to Open:

REMOVE AND OPEN PACKAGE

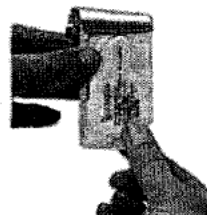
- 1.** Cut along scissor cut line to separate unit



- 2.** Turn unit over and cut corner at bulb end



- 3.** From cut corner, peel backing completely off from bottom to top



- 4.** Remove the applicator

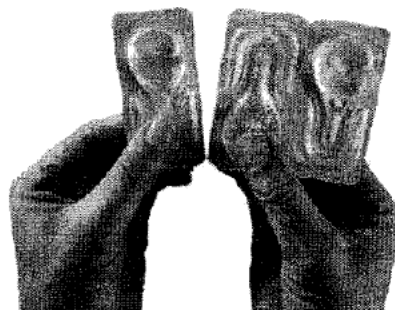


OPEN APPLICATOR

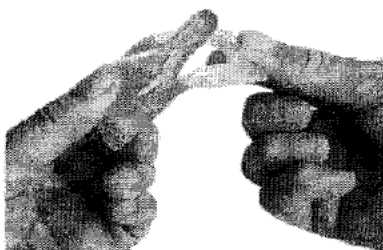
Hold upright with foil side away from you and snap applicator tip back to open.

{Begin Package insert for alternate CRP blister applicator (3-Count)}

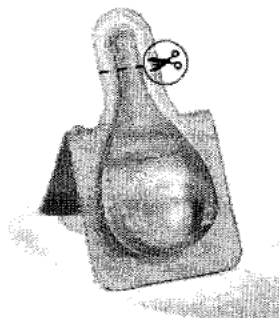
1 Tear through perforation



2 Fold back the safety tab

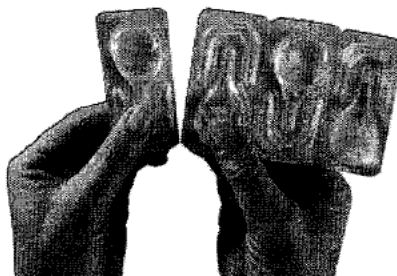


3 Cut with scissors to open applicator

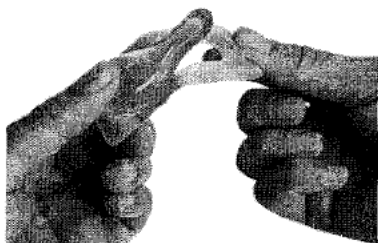


{Begin Package insert for alternate CRP blister applicator (4-Count)}

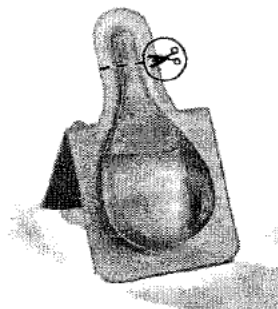
1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator



{Begin Inside Carton Panels or Continuation of Package Insert for Cartons without Inside Panels}

Promika ZoGuard Plus for Dogs

{One of the following statements will appear on the inside panel of the carton.}

For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR}
For use ONLY on dogs and puppies 5[-] [to] 22 lbs and over 8 weeks of age {OR}
For use ONLY on dogs & puppies 5[-] [to] 22 lbs and over 8 weeks of age {OR}
ONLY For Dogs [23[-][to] 44 lbs] [45[-][to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR}
ONLY For Dogs & Puppies 8 weeks or older and 5[-][to] 22 lbs {OR}
ONLY For Dogs & Puppies 8 weeks or older & 5[-][to] 22 lbs

[Brand Name] [This product] contains Fipronil and (S)-Methoprene [insect growth regulator] [IGR] to effectively kill fleas and ticks [including those that may transmit Lyme disease]. [The active ingredients in [Brand Name][This product] features a formula developed for fast acting [and long lasting for up to [4 weeks][30 days][1 month]] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

{Text below is only for Inside Carton Panels}

How to Open

Refer to package insert for directions on how to open package.

{Remaining text below is for Inside Carton Panels and for Package Insert for Cartons without Inside Panels}

How to Apply

Remove product applicator from the package.

Separate one applicator from the others. Hold the applicator with notched end pointing up and away from the face and body.

[Snap the outline of the tip back to allow access to the [dotted tip of the] applicator]]. {OR}

[Snap the applicator tip [backwards] [across the marked line] [to allow access to the] [dotted tip] [notches]].

{OR} [Holding the applicator away from your and your dog's eyes, snap the applicator tip [at notched line] to open.] Invert applicator over dog and use open end to part dog's hair.

[Squeeze applicator firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.]

Allow the area to dry. Avoid contact with treated area until dry. Use only one applicator per treatment.

RESTRICTIONS

Do not allow your dog to ingest this product.

Do not use on puppies under 8 weeks of age and less than [5][23][45][89] lbs.

Use entire contents of applicator on each dog.

Do not split one applicator between dogs.

Do not use multiple applicators on one dog.

Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.

Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.

Be sure your dog is dry before application and keep your dog dry for 24 hours after application.

Do not bathe your dog for 24 hours after application.

Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Do not apply more frequently than once every [30 days][4 weeks][month].

[Optional pictogram]



[Look at the Label (Look at the Label icon)

[Easy] 6 Step [Easy] [Spot On] [Topical]

Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate dogs after [treatment] [application] from other animals to avoid chance of ingestion
- [6] Do NOT split applicators between dogs [and use the ENTIRE applicator contents]

[Manufactured For][Distributed By]:

[Promika, LLC.

5000 CentreGreen Way, Suite 100

Cary, NC 27513]

EPA Reg. No. 91300-5

EPA Est. No. XXXX-XXX-XXX

[WARRANTY] [LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of [Company]. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, [Company] makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither [Company], the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Do not remove applicator from the pack until ready to use. Store in a cool (below 77°F [25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. **If empty:** Offer for recycling if available **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

{Optional recycling graphic}



{End Inside Panels of Carton or Package Insert for Cartons without Inside Panels}

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{SIDE PANEL 1}

[[Brand name][This product]. [Three][Four][Six][Eight][Twelve] month supply. ONLY for Dogs & Puppies 8 weeks or older and [5[-] [to] 22 lbs.] [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs]

{SIDE PANEL 2}

[[Brand name][This product]. ONLY for Dogs & Puppies 8 weeks or older and [5[-] [to] 22 lbs] [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs]

{SIDE PANEL 3}

[[Brand name][This product]. ONLY for Dogs & Puppies 8 weeks or older and [5[-] [to] 22 lbs] [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs]






















{SIDE PANEL 4}

[Brand name][This product]. ONLY for Dogs & Puppies 8 weeks or older and [5[-] [to] 22 lbs] [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs]

[BAR CODE AREA]


[Lot code; only number will appear]

{Optional graphics below may or may not appear anywhere on finished label}

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	

{May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from an applicator on front, side, back, inside carton panels.}

{START –APPLICATOR LABEL - for applicator inside a CRP blister and for the CRP blister applicator}

<p>{Brand Name}</p> <p>For Dogs [X-Y] lbs and ≥ 8 wks</p> <p>fipronil 9.8%, (S)-methoprene 8.8%</p> <p>0.023 fl oz {or} 0.045 fl oz {or} 0.091 fl oz {or} 0.136 fl oz</p> <p>Lot/Batch No. {only number will appear}</p>	 <p>KEEP OUT OF REACH OF CHILDREN CAUTION. Read accompanying label before use. [Use scissors to open.] EPA REG. No. 91300-5</p>
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{END – APPLICATOR LABEL - for applicator inside a CRP blister and for the CRP blister applicator }

{START – OUTER BLISTER LABEL – for applicator inside a CRP blister}

<p>{Brand Name}</p> <p>For Dogs [X-Y] lbs ≥ 8 wks</p> <p>fipronil 9.8%, (S)-methoprene 8.8%</p> <p>0.023 fl oz {or} 0.045 fl oz {or} 0.091 fl oz {or} 0.136 fl oz</p> <p>Lot/Batch No. {only number will appear}</p>	<p>KEEP OUT OF REACH OF CHILDREN CAUTION. For External Use Only. Read accompanying label before use. EPA REG. No. 91300-5 {label code}</p>
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{END – OUTER BLISTER LABEL – for applicator inside a CRP blister}

{START - IMAGE FOR OUTER BLISTER LABEL – for applicator inside the CRP blister}



{END – OUTER BLISTER LABEL – for applicator inside the CRP blister}

{Optional Marketing Claims}

Mosquitoes

1. Kills mosquitoes [within 48 hours for up to 28 days, with monthly application]

Chewing Lice

2. Kills chewing lice
3. Rapid elimination of chewing lice infestations
4. A once monthly application required to control chewing lice

Adult Fleas

5. Kills [adult] Fleas
6. Kills newly emerged adult Fleas before they lay eggs
7. Kills Adult Fleas, which may be a source of flea allergy dermatitis
8. Kills Fleas Up to [4 weeks] [1 month] [30 days]!
9. If dog is a high risk for flea reinfestation, a once month application may be needed

Multiple Infestations

10. Kills chewing lice [and controls mites that may cause sarcoptic mange]
11. Flea [&] [and] Tick Control for Dogs [&] [and] Puppies [5[-] [to] 22 lbs] [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks [&] [and] older
12. Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]
13. Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]
14. Kills Fleas, Ticks [&] [and] [Mosquitoes]
15. Breaks the Flea Life Cycle [when used monthly]
16. Monthly protection from flea, tick, [mosquito], chewing lice and flea egg
17. Monthly protection from flea, tick, [mosquito] and chewing lice
18. Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice
19. [Seven] [7] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae
20. [Six] [6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae
21. [Five] [5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs & flea larvae
22. [Six] [6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs & flea larvae
23. [Five] [5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs & flea larvae
24. [Four] [4] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs
25. [4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!
26. [Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]
27. [Four [4] Week] [1 month] Flea, Tick, [Mosquito] and Chewing Lice Control
28. Use [Brand Name][This product] monthly to break the flea life cycle
29. Use [Brand Name][This product] monthly to control ticks and chewing lice
30. Monthly protection of flea, tick, [mosquito,] flea egg, flea larvae and chewing lice
31. Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]
32. Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!
33. Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!
34. Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]

Ticks

35. Kills Ticks including those that may transmit Lyme disease
36. Kills Ticks for Up to [4 weeks] [1 month] [30 days]!
37. Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days]] [per application]
38. Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]
39. Kills [brown dog ticks [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks][,][and deer

- ticks] [for up to [4 weeks] [1 month] [30 days]
40. Kills American Dog Ticks [*Dermacentor variabilis*] for up to [4 weeks] [1 month] [30 days]!

Flea Eggs and Larvae

- 41. Controls flea reinfestation
- 42. Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae.
- 43. Effectively controls all stages of the flea [including adult fleas, flea eggs, flea larvae] and prevents the development of flea pupae
- 44. Effective against all stages of the flea [including adult fleas, flea eggs, flea larvae] and prevents the development of flea pupae
- 45. If dog is a high risk for flea reinfestation, a once month application may be needed
- 46. Prevents from developing, flea eggs [larvae] [pupae]
- 47. With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle
- 48. With (S)-methoprene to Break Flea Life Cycle
- 49. With Insect Growth Regulator [IGR] to Break Flea Life Cycle
- 50. Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle Kills Flea Eggs & Flea Larvae!
- 51. Prevents Flea Eggs From Developing Into Biting Adults
- 52. Prevents all stages of the flea life cycle from developing
- 53. Controls reinfestation of fleas
- 54. Effective against all stages of the flea life cycle
- 55. Effectively controls all stages of the flea life cycle

All Others

- 56. Can be used on puppies [5-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.] and 8 weeks of age and older
- 57. For Dogs & Puppies [5-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.] and 8 weeks of age or older
- 58. For Dogs [and Puppies] [5-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.] and 8 weeks of age or older
- 59. Convenient spot treatment
- 60. Fast Acting
- 61. Easy to Use [Application]
- 62. Best if used year round!
- 63. For year-round protection, apply [Brand Name] monthly
- 64. (ICON Showing [4 week] [1 month] [30 day] Protection)
- 65. Apply monthly
- 66. Prevents reinfestation of listed pests for [4 weeks] [1 month]
- 67. Apply once every [4 weeks] [month] [30 days]!
- 68. [4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
- 69. [Three Applications][Six Applications][12 Applications]
- 70. [3 Month Supply][6 Month Supply][12 Month Supply]
- 71. Controls mites that may cause sarcoptic mange
- 72. Waterproof
- 73. Effective after bathing and exposure to water and sunlight
- 74. Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]
- 75. Fipronil (9.8%) + (S)-methoprene (8.8%)
- 76. Controls and prevents infestation of listed pests for [4 weeks][1 month]
- 77. Controls existing infestation and prevents establishment of additional infestation of listed pests
- 78. Lift [here] for more information
- 79. Open [here] for more information
- 80. Image of an arrow to show Open here for more information
- 81. {When used, all three optional statements will appear together.}
Contains Fipronil and (S)-methoprene, the active ingredients used in FRONTLINE® Plus for Dogs
Frontline is a registered trademarks of Merial
(Brand Name) is not manufactured or distributed by Merial

Sublabel 2: Promika ZoGuard Plus for Dogs {single applicator}

[text in [] denotes optional language]

{text in {} denotes location of text on packaging, notes to reviewer, text that will not be on final label}

(text in () appears on label)

{Start Front Panel of Foil Pouch; package is single applicator in heat-sealed foil pouch}

Promika ZoGuard Plus for Dogs
[Alternate brand name: Fortress Defense for Dogs; Heritage Plus for Dogs]

{The word "Dogs" in the product name will be 75% of the height of the largest letter in the primary brand name.}

{Large clear picture of dog in appropriate breed/weight class on front panel to be included}



{a 1.5cm x 1.5cm cat prohibition icon in a box located at the lower right hand corner of the front panel in yellow with black images}

{One of the following statements will appear on the front panel.}

For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR}
For use ONLY on dogs and puppies 5[-] [to] 22 lbs and 8 weeks or older {OR}
For use ONLY on dogs & puppies 5[-] [to] 22 lbs and 8 weeks or older {OR}
ONLY For Dogs [23[-][to] 44 lbs] [45[-][to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR}
ONLY For Dogs & Puppies 8 weeks or older and 5[-][to] 22 lbs {OR}
ONLY For Dogs & Puppies 8 weeks or older & 5[-][to] 22 lbs

{Optional Marketing Claim}

[1][One] Month Supply]

[1][One][Application]

{When used, all three optional statements below will appear together on the same panel.}

[Contains Fipronil and (S)-Methoprene, the active ingredients used in FRONTLINE® Plus for Dogs]

[Frontline is a registered trademark of Merial]

[(Brand Name) is not manufactured or distributed by Merial, seller of Frontline® Plus for Dogs]

{See optional graphics on pages 24-25 of this label that may or may not appear on front panel of carton}

ACTIVE INGREDIENTS:

Fipronil..... 9.80%

(S)-Methoprene..... 8.80%

OTHER INGREDIENTS: 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Precautionary Statements

See Package Insert for First Aid and Complete Directions for Use

Net Contents: X fl. oz. [(mL)]

[1 applicator containing 0.023 fl oz (0.67 mL)]

[1 applicator containing 0.045 fl oz (1.34 mL)]

[1 applicator containing 0.091 fl oz (2.68 mL)]

[1 applicator containing 0.136 fl oz (4.02 mL)]

{END – Front Panel of Foil Pouch}

{BACK PANEL OF FOIL POUCH}

Promika ZoGuard Plus for Dogs

[In Case of Emergency, call: XXX-XXX-XXXX] [Non-Emergency, call XXX-XXX-XXXX] [Formulated in USA]

[Manufactured For][Distributed By]:

[Promika, LLC.

5000 CentreGreen Way, Suite 100

Cary, NC 27513]

EPA Reg. No. 91300-5

EPA Est. No. XXXX-XXX-XXX

READ ENTIRE PRODUCT LABEL INSIDE THE POUCH BEFORE EACH USE.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product. This product is not a substitute for prescribed Heartworm preventative.

PRODUCT INFORMATION

Use [Brand Name] [this product] monthly for control of fleas, ticks, [and] chewing lice, [and mosquitoes]. [Studies show that] [Brand Name] [this product] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[, [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Avoid contact with treated area until dry. Do not reapply for [30 days] [4 weeks][1 month]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs.

{The following Side Effects text in a box will be placed in the lower right hand corner of back panel immediately above the cat warning box.}

Side Effects (Dogs): Monitor your dog after application. Some dogs may experience temporary startle effects when any product is applied. Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. In some cases gastrointestinal signs such as vomiting and diarrhea may occur. If these or other side effects occur, consult your veterinarian or call SafetyCall at 1-844-685-9173. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application.

{a 1.5 cm x 1.5 cm cat prohibition icon and warning text in a box, black on yellow background, will be placed on the lower right hand corner of back panel.}



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[BAR CODE AREA]

[Lot code; only number will appear]

{END – BACK PANEL OF FOIL POUCH}

{Begin Foil-Line Pouch Insert}

Promika ZoGuard Plus for Dogs

{The following statements will appear on the pouch insert.}

For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR} For use ONLY on dogs and puppies 5[-] [to] 22 lbs and over 8 weeks of age {OR} For use ONLY on dogs & puppies 5[-] [to] 22 lbs and over 8 weeks of age {OR} ONLY For Dogs [23[-][to] 44 lbs] [45[-][to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR} ONLY For Dogs & Puppies 8 weeks or older and 5[-][to] 22 lbs {OR} ONLY For Dogs & Puppies 8 weeks or older & 5[-][to] 22 lbs
--

ACTIVE INGREDIENTS:

Fipronil..... 9.80%

(S)-Methoprene..... 8.80%

OTHER INGREDIENTS: 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product. This product is not a substitute for prescribed Heartworm preventative.

FIRST AID	
If in eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
If swallowed	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. <u>Do not give anything by mouth to an unconscious person.</u>
If on skin	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, you may contact SafetyCall at 1-844-685-9173 seven days a week, 24-hours a day.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG,

READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs.

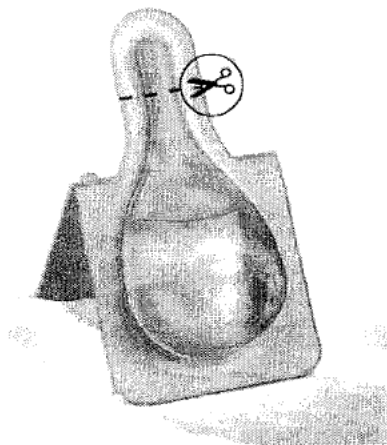
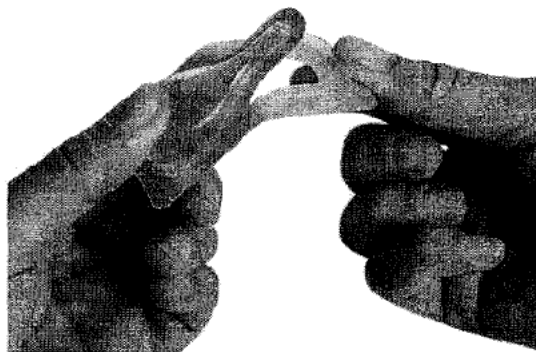
Side Effects (Dogs): Monitor your dog after application. Some dogs may experience temporary startle effects when any product is applied. Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. In some cases gastrointestinal signs such as vomiting and diarrhea may occur. If these or other side effects occur, consult your veterinarian or call SafetyCall at 1-844-685-9173. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application.

PRODUCT INFORMATION

[[Brand Name] [This product] contains Fipronil and (S)-Methoprene [insect growth regulator] [IGR] to effectively kill fleas and ticks [including those that may transmit Lyme disease]. [The active ingredients in [Brand Name][This product] features a formula developed for fast acting [and long lasting for up to [4 weeks][30 days][1 month]] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.] Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Avoid contact with treated area until dry. Do not reapply for [30 days] [4 weeks][1 month].

How to Open:

1 Fold back the safety tab



2 Cut with scissors to open applicator

How to Apply

Remove product applicator from the package.

Separate one applicator from the others. Hold the applicator with notched end pointing up and away from the face and body.

[Snap the outline of the tip back to allow access to the [dotted tip of the] applicator]]. {OR}
[Snap the applicator tip [backwards] [across the marked line] [to allow access to the] [dotted tip] [notches]].
{OR} [Holding the applicator away from your and your dog's eyes, snap the applicator tip [at notched line] to open.] Invert applicator over dog and use open end to part dog's hair.
[Squeeze applicator firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.]

Allow the area to dry. Avoid contact with treated area until dry. Use only one applicator per treatment.

RESTRICTIONS

Do not allow your dog to ingest this product.
Do not use on puppies under 8 weeks of age and less than [5][23][45][89] lbs.
Use entire contents of applicator on each dog.
Do not split one applicator between dogs.
Do not use multiple applicators on one dog.
Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.
Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
Be sure your dog is dry before application and keep your dog dry for 24 hours after application.
Do not bathe your dog for 24 hours after application.
Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.
Do not apply more frequently than once every [30 days][4 weeks][month].

[Optional pictogram]



[Look at the Label (Look at the Label icon)

[Easy] 6 Step [Easy] [Spot On] [Topical]

Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate dogs after [treatment] [application] from other animals to avoid chance of ingestion
- [6] Do NOT split applicators between dogs [and use the ENTIRE applicator contents]

[Promika, LLC.

5000 CentreGreen Way, Suite 100

Cary, NC 27513]

EPA Reg. No. 91300-5

[WARRANTY] [LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of [Company]. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, [Company] makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither [Company], the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Do not remove applicator from the pack until ready to use. Store in a cool (below 77°F [/[25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. **If empty:** Offer for recycling if available **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

{Optional recycling graphic}



{End Foil Pouch Insert}

{START – CRP BLISTER APPLICATOR LABEL}

<p>{Brand Name}</p> <p>For Dogs [X-Y] lbs and ≥ 8 wks</p> <p>fipronil 9.8%, (S)-methoprene 8.8%</p> <p>0.023 fl oz {or} 0.045 fl oz {or} 0.091 fl oz</p> <p>{or} 0.136 fl oz</p> <p>Lot/Batch No. {only number will appear}</p>	<p>KEEP OUT OF REACH OF CHILDREN</p> <p>CAUTION. Read accompanying label before use.</p> <p>[Use scissors to open.]</p> <p>EPA REG. No. 91300-5</p>
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{END – CRP BLISTER APPLICATOR LABEL}

{Optional Marketing Claims}

Mosquitoes

1. Kills mosquitoes [within 48 hours for up to 28 days, with monthly application]

Chewing Lice

2. Kills chewing lice
3. Rapid elimination of chewing lice infestations
4. A once monthly application required to control chewing lice

Adult Fleas

5. Kills [adult] Fleas
6. Kills newly emerged adult Fleas before they lay eggs
7. Kills Adult Fleas, which may be a source of flea allergy dermatitis
8. Kills Fleas Up to [4 weeks] [1 month] [30 days]!
9. If dog is a high risk for flea reinfestation, a once month application may be needed

Multiple Infestations

10. Kills chewing lice [and controls mites that may cause sarcoptic mange]
11. Flea [&] [and] Tick Control for Dogs [&] [and] Puppies [5[-] [to] 22 lbs] [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks [&] [and] older
12. Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]
13. Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]
14. Kills Fleas, Ticks [&] [and] [Mosquitoes]
15. Breaks the Flea Life Cycle [when used monthly]
16. Monthly protection for flea, tick, [mosquito], chewing lice and flea egg
17. Monthly protection from flea, tick, [mosquito] and chewing lice
18. Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice
19. [Seven] [7] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae
20. [Six] [6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae
21. [Five] [5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs & flea larvae
22. [Six] [6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs & flea larvae
23. [Five] [5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs & flea larvae
24. [Four] [4] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs
25. [4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!
26. [Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]
27. [Four [4] Week] [1 month] Flea, Tick, [Mosquito] and Chewing Lice Control
28. Use [Brand Name][This product] monthly to break the flea life cycle
29. Use [Brand Name][This product] monthly to control ticks and chewing lice
30. Monthly protection from flea, tick, [mosquito,] flea egg, flea larvae and chewing lice
31. Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]
32. Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!
33. Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!
34. Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]

Ticks

35. Kills Ticks including those that may transmit Lyme disease
36. Kills Ticks for Up to [4 weeks] [1 month] [30 days]!
37. Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days]] [per application]
38. Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]
39. Kills [brown dog ticks [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks][,][and deer

- ticks] [for up to [4 weeks] [1 month] [30 days]
40. Kills American Dog Ticks [*Dermacentor variabilis*] for up to [4 weeks] [1 month] [30 days]!



Flea Eggs and Larvae

- 41. Controls flea reinfestation
- 42. Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae.
- 43. Effectively controls all stages of the flea [including adult fleas, flea eggs, flea larvae] and prevents the development of flea pupae
- 44. Effective against all stages of the flea [including adult fleas, flea eggs, flea larvae] and prevents the development of flea pupae
- 45. If dog is a high risk for flea reinfestation, a once month application may be needed
- 46. Prevents from developing, flea eggs [larvae] [pupae]
- 47. With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle
- 48. With (S)-methoprene to Break Flea Life Cycle
- 49. With Insect Growth Regulator [IGR] to Break Flea Life Cycle
- 50. Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle Kills Flea Eggs & Flea Larvae!
- 51. Prevents Flea Eggs From Developing Into Biting Adults
- 52. Prevents all stages of the flea life cycle from developing
- 53. Controls reinfestation of fleas
- 54. Effective against all stages of the flea life cycle
- 55. Effectively controls all stages of the flea life cycle

All Others

- 56. Can be used on puppies [5-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.] and 8 weeks of age and older
- 57. For Dogs [&][and] Puppies [5-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.] and 8 weeks of age or older
- 58. For Dogs [and Puppies] [5-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.] and 8 weeks of age or older
- 59. Convenient spot treatment
- 60. Fast Acting
- 61. Easy to Use [Application]
- 62. Best if used year round!
- 63. For year-round protection, apply [Brand Name] monthly
- 64. (ICON Showing [4 week] [1 month] [30 day] Protection)
- 65. Apply monthly
- 66. Prevents reinfestation of listed pests for [4 weeks] [1 month]
- 67. Apply once every [4 weeks] [month] [30 days]!
- 68. [4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
- 69. [Once Application]
- 70. [1 Month Supply]
- 71. Controls mites that may cause sarcoptic mange
- 72. Waterproof
- 73. Effective after bathing and exposure to water and sunlight
- 74. Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]
- 75. Fipronil (9.8%) + (S)-methoprene (8.8%)
- 76. Controls and prevents infestation of listed pests for [4 weeks][1 month]
- 77. Controls existing infestation and prevents establishment of additional infestation of listed pests
- 78. Open [here] for more information
- 79. Image of an arrow to show Open here for more information
- 80. {When used, all three optional statements will appear together.}
Contains Fipronil and (S)-methoprene, the active ingredients used in FRONTLINE® Plus for Dogs Frontline is a registered trademarks of Merial
(Brand Name) is not manufactured or distributed by Merial

(Optional graphics below may or may not appear anywhere on finished label)

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	

Breeden-Alemi, Julie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Monday, January 08, 2018 6:26 PM
To: Breeden-Alemi, Julie
Cc: Davis, Kable; IVB1
Subject: RE: Reg. No. 91300-5 and 91300-6

Thanks, Julie.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: January 08, 2018 3:12 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: Reg. No. 91300-5 and 91300-6

Hi Ann,

Please find attached the signed letters and stamped labels for Reg. No. 91300-5 and -6 adding CRP.

Courtesy note:

For Reg. No. 91300-5 on the bottom of page 14 of the label there is a typo with regard to page numbers: {See optional graphics on pages 24-25 of this label that may or may not appear on front panel of carton} There is no page 25. This can be revised by non-notification.

On Reg. No. 91300-6 a similar notation is made on page 12 of the label referring to pages 18-19. Just check that one to verify it says what you want it to say.

Thank you, Ann. Have a wonderful week!

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511
Office: S-7216, Mail Code: 7505P

-5

Breeden-Alemi, Julie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Thursday, January 04, 2018 2:17 PM
To: Breeden-Alemi, Julie
Subject: RE: Reg. No. 91300-5
Attachments: 20180104 91300-5 8570-35 Public.pdf; 20180104 91300-5 8570-35 Agency.pdf

Julie,

The revised matrices are attached.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: January 04, 2018 1:53 PM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: RE: Reg. No. 91300-5

Hi Ann,

Thank you for the documents. I am working to finish these up and move them forward for you today. For Reg. No. 91300-5 it looks like three line items were removed in the second CRP section on page 4 of the matrix dated Dec. 28, 2017 when compared to the original matrix dated Sept. 16, 2016. Two of those started with KVS and then the third one ending in 301. They were grouped together on the 2016 matrix. The MRID ending in 301 is listed in the CRP review dated 29 September 2017. Can you check on this? Also, the date on the Certification with Respect to Citation of Data form needs to match that on the submitted matrix. If you are able to check into this today, only the date on the matrix would need revision as the Certification form is dated 1/4/18.

Thanks! I'm available by phone from 4-4:30 this afternoon if needed.

Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
703.347.0511

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Thursday, January 04, 2018 11:36 AM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: IVB1 <IVB1@epa.gov>
Subject: RE: Reg. No. 91300-5 and -6

Julie,

Attached is the dog label with that minor correction made. Also attached are the Certifications (8570-34) and updated data matrices (Agency and Public versions) for both 91300-5 and 91300-6. Thanks for all your help with this label amendment!

Ann

From: Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]
Sent: December 29, 2017 6:33 AM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: IVB1 <IVB1@epa.gov>
Subject: RE: Reg. No. 91300-5 and -6

Good morning Ann,

Thank you for the responses and labels. I'll send the packages forward as soon as I receive the other materials as outlined below, and we can finish these up for you!

There is one courtesy comment... it is up to you if you want to go ahead and make the revision. On page 8 the last text claim where the word "weeks" is repeated: [30 days][4 weeks weeks][month].

If you want to make that revision, go ahead and send it over. A clean copy is all that is necessary so long as that is the only change.

Thanks, and Happy New Year!

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1

From: Ann Tillman [<mailto:Ann@PyxisRC.com>]
Sent: Thursday, December 28, 2017 3:03 PM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: IVB1 <IVB1@epa.gov>
Subject: RE: Reg. No. 91300-5 and -6

Julie,

I inserted some comments below in response to your questions and comments.

Ann

From: Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]
Sent: December 27, 2017 5:12 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: IVB1 <IVB1@epa.gov>
Subject: RE: Reg. No. 91300-5 and -6

Hi Ann,

Thank you for sending in the labels! Please see below for items remaining for each product.

I understand there were some complex factors with these actions regarding the manufacturing sites about which you've had conversations with the CRP team. Is that correct? Currently there are more MRIDs on the matrices for both products than listed in the current CRP review most of which are associated with the original CRP packaging. Is that original packaging obsolete for these products and are those associated MRIDs linked to the current packaging such that they should remain on the matrices? OR can the MRIDs listed in the current reviews supporting the current packaging on the label stand alone? Thanks for clarifying the circumstances. The original CRP remains as an option (the original CRP photos are still on the label) so I will not remove any MRIDs from the data matrix for that package.

-5

Breeden-Alemi, Julie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Thursday, December 28, 2017 3:03 PM
To: Breeden-Alemi, Julie *Resub*
Cc: IVB1
Subject: RE: Reg. No. 91300-5 and -6
Attachments: 20171228 Promika ZoGuard Plus for Dogs Label .pdf; 20171228 Promika ZoGuard Plus for Dogs Label chgs trkd.pdf

Julie,

I inserted some comments below in response to your questions and comments.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: December 27, 2017 5:12 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: IVB1 <IVB1@epa.gov>
Subject: RE: Reg. No. 91300-5 and -6

Hi Ann,

Thank you for sending in the labels! Please see below for items remaining for each product.

I understand there were some complex factors with these actions regarding the manufacturing sites about which you've had conversations with the CRP team. Is that correct? Currently there are more MRIDs on the matrices for both products than listed in the current CRP review most of which are associated with the original CRP packaging. Is that original packaging obsolete for these products and are those associated MRIDs linked to the current packaging such that they should remain on the matrices? OR can the MRIDs listed in the current reviews supporting the current packaging on the label stand alone? Thanks for clarifying the circumstances. The original CRP remains as an option (the original CRP photos are still on the label) so I will not remove any MRIDs from the data matrix for that package.

Reg. No. 91300-5

1. Label: There are just two comments, one is on page 8, and one which occurs in a few locations having to do with weight ranges. See attached for comments. The revised labels are attached.
2. Matrix: Unless I am missing it, I am unable to find MRIDs 49794001 and 49794002 on the current data matrix (9/16/16) on file. Now that I have the correct MRIDs, I will revise the data matrix so the 9/12/17 matrix should be discarded. As stated in the CRP review (attached for your convenience) these MRIDs should be on the matrix. In addition we will need a revised Certification with Respect to Data Citation form to match the date of the revised matrix. I will send you a revised matrix and Certification once we get the offer-to-pay letters sent out, likely not until next week.
 - a. You sent a matrix also dated 9/16/16 on 9/12/17, but the CRP MRIDs listed on that version doesn't match the original dated 9/16/16 nor does it match the current review. If you think a phone call would help clarify some of the confusion, please let me know. I am in the office through Friday this week and then next week Wed-Friday.

Reg. No. 91300-6

1. Unless I am missing it, I am unable to find MRID 49794001 on the current data matrix (9/2/16) on file. As stated in the CRP review (attached for your convenience) this MRID should be on the matrix. In addition we will need a

revised Certification with Respect to Data Citation form to match the date on the revised matrix. The same comments for the dog product applies to the cat product. I did not update that 9/2/16 matrix but will do so now that I have the accepted MRIDs and will send to you next week.

Thanks and have a wonderful evening!

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1

From: Ann Tillman [<mailto:Ann@PyxisRC.com>]
Sent: Tuesday, December 12, 2017 9:40 PM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: IVB1 <IVB1@epa.gov>
Subject: RE: Reg. No. 91300-5 and -6

Julie,

I am so sorry for the delay in getting these labels back to you! I was on vacation when you sent the email and I dropped the ball and didn't handle. I've attached the revised versions (clean and changes tracked versions). I hope I made the changes as you requested. I did make the global change to the Promika address (note: CentreGreen is one word and spelled correctly!). Let me know if you see any other changes to the labels or have questions especially on the labeling for the two different CRPs. Thanks.

Ann

From: Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]
Sent: November 02, 2017 3:48 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: IVB1 <IVB1@epa.gov>
Subject: Reg. No. 91300-5 and -6


Hi Ann,

Attached are the CRP reviews and a few label comments for Reg. No. 91300-5 and -6. Please let me know if you have any questions. I am in the office tomorrow and next week Monday-Wednesday. Otherwise, please send revised labels both highlighted and clean in readable electronic pdf format.

Thanks, Ann, and have a great rest of the day!
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511
Office: S-7216, Mail Code: 7505P

Breeden-Alemi, Julie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Tuesday, December 12, 2017 9:40 PM 
To: Breeden-Alemi, Julie
Cc: IVB1
Subject: RE: Reg. No. 91300-5 and -6
Attachments: 20171212 Promika ZoGuard Plus for Cats Label.pdf; 20171212 Promika ZoGuard Plus for Cats Label chgs trkd.pdf; 20171212 Promika ZoGuard Plus for Dogs Label.pdf; 20171212 Promika ZoGuard Plus for Dogs Label chgs trkd.pdf

Julie,

I am so sorry for the delay in getting these labels back to you! I was on vacation when you sent the email and I dropped the ball and didn't handle. I've attached the revised versions (clean and changes tracked versions). I hope I made the changes as you requested. I did make the global change to the Promika address (note: CentreGreen is one word and spelled correctly!). Let me know if you see any other changes to the labels or have questions especially on the labeling for the two different CRPs. Thanks.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: November 02, 2017 3:48 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: IVB1 <IVB1@epa.gov>
Subject: Reg. No. 91300-5 and -6

Hi Ann,

Attached are the CRP reviews and a few label comments for Reg. No. 91300-5 and -6. Please let me know if you have any questions. I am in the office tomorrow and next week Monday-Wednesday. Otherwise, please send revised labels both highlighted and clean in readable electronic pdf format.

Thanks, Ann, and have a great rest of the day!
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511
Office: S-7216, Mail Code: 7505P

Breeden-Alemi, Julie

From: Roe, Lindsay
Sent: Thursday, September 28, 2017 3:24 PM
To: Ann Tillman
Cc: Breeden-Alemi, Julie
Subject: RE: CRP Cert for ZoGuard for Dogs
Attachments: Comments #2 91300-5 2170912 Promika CRP Cert 34 count_rev (002).pdf

Hi, Ann.

The revision that we were discussing should have been made to the most recent version of the certification letter. I think that you used a previous version. I've attached the "most recent" version I'm talking about to this message for your reference, with the paragraph I was referring to highlighted.

-Lindsay

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Thursday, September 28, 2017 3:18 PM
To: Roe, Lindsay <Roe.Lindsay@epa.gov>
Subject: RE: CRP Cert for ZoGuard for Dogs

Here you go.

Ann

From: Roe, Lindsay [mailto:Roe.Lindsay@epa.gov]
Sent: September 28, 2017 3:08 PM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: RE: CRP Cert for ZoGuard for Dogs

Yes, please. Thanks for checking.

-Lindsay

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Thursday, September 28, 2017 2:58 PM
To: Roe, Lindsay <Roe.Lindsay@epa.gov>
Subject: CRP Cert for ZoGuard for Dogs

Lindsay,

I updated the CRP Cert but did you need me to re-date it?

Ann

Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516

Breeden-Alemi, Julie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Tuesday, September 12, 2017 1:43 PM
To: Breeden-Alemi, Julie
Subject: RE: Promika ZoGuard Plus for Dogs, 91300-5
Attachments: 20160916 91300-5 8570-35 Agency rev.pdf

Julie,

The data matrix is attached.

Ann

Resub

From: Ann Tillman
Sent: September 12, 2017 12:20 PM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: Promika ZoGuard Plus for Dogs, 91300-5

Julie,

Sorry about that... CRP Cert is attached. I will revise the matrix to change the date back to the last time offers-to-pay were sent so no new Certification is needed. We are not sending new offers-to-pay since I did not add any new MRID to the matrix.

matrix does not include original matrix from 2016

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: September 12, 2017 11:34 AM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: RE: Promika ZoGuard Plus for Dogs, 91300-5

Hi Ann,

Thanks so much. I received a data matrix, but the revised CRP Certification wasn't attached. Could you please resend? Along with the matrix we would need the revised Certification with Respect to Data Citation form to match the date on the revised matrix.

Thanks so much!

Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Tuesday, September 12, 2017 11:09 AM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: Promika ZoGuard Plus for Dogs, 91300-5

Resub

Julie,

Lyndsay and I spoke this morning about the CRP Certification for this product which was part of the label amendment I submitted August 3, 2017. Attached, please find the revised CRP Certification. Lyndsay said you might need an updated data matrix so I am attaching that file, too. Let me know if you need anything further for this label amendment. Thanks!

Ann

*Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com*



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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Promika, LLC c/o Pyxis Regulatory 4110 136th St. Ct. NW Gig Harbor, WA 253-8537369	EPA Registration Number/File Symbol/ 91300-5
Active Ingredient(s) and/or representative test compound(s) Fipronil, S-methoprene	Date Jan. 04, 2018
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor nonfood	Product Name Promika ZoGuard Plus for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statements (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have including with this form a list of companies send offer of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (II) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date Jan. 04, 2018	Typed or Printed Name and Title Ann M. Tillman Agent
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DATA MATRIX

Date Jan. 4, 2018	EPA Reg. No./File Symbol 91300-5	Page 1 of 14
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	49770001	Promika, LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	49770001	Promika, LLC	OWN	
830.1620	Description of Production Process				Not Required ¹
830.1650	Description of Formulation Process	49770001	Promika, LLC	OWN	
830.1670	Discussion of Formation of Impurities	49770001	Promika, LLC	OWN	
830.1700	Preliminary Analysis				Not required ¹
830.1750	Certified Limits	49770001	Promika, LLC	OWN	
830.1800	Enforcement Analytical Method	49769902	Promika, LLC	OWN	See Endnote ²
830.6302	Color	49770002	Promika, LLC	OWN	
830.6303	Physical State	49770002	Promika, LLC	OWN	
830.6304	Odor	49770002	Promika, LLC	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not required ¹
830.6314	Oxidation/Reduction: Chemical Incompatibility	49770002	Promika, LLC	OWN	Waiver ³
830.6315	Flammability	49770002	Promika, LLC	OWN	
830.6316	Explosibility	49770002	Promika, LLC	OWN	Waiver ⁴

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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DATA MATRIX

Date Jan. 4, 2018	EPA Reg. No./File Symbol 91300-5	Page 2 of 14
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage Stability	49770002	Promika, LLC	OWN	PRN 92-5 ⁵
830.6319	Miscibility				Not Applicable ⁶
830.6320	Corrosion Characteristics	49770002	Promika, LLC	OWN	PRN 92-5 ⁴
830.6321	Dielectric Breakdown Voltage				Not Applicable ⁵
830.7000	pH	49770002	Promika, LLC	OWN	
830.7050	UV/Visible Absorption				Not Required ¹
830.7100	Viscosity	49770002	Promika, LLC	OWN	
830.7200	Melting Point/Melting Range				Not Required ¹
830.7220	Boiling Point/Boiling Range				Not Required ¹
830.7300	Density/Relative Density/Bulk Density	49770002	Promika, LLC	OWN	
830.7370	Dissociation Constants in Water				Not Required ¹
830.7520	Particle Size, Fiber Length, and Diameter Distribution			OWN	Waiver ⁵
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not Required ¹
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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DATA MATRIX

Date Jan. 4, 2018	EPA Reg. No./File Symbol 91300-5	Page 3 of 14
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not Required ¹
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not Required ¹
870.1100	Acute Oral Toxicity: Rat	44942004		OLD	
870.1200	Acute Dermal Toxicity: Rat	44942005		OLD	
870.1300	Acute Inhalation Toxicity: Rat	49770003	Promika, LLC	OWN	Waiver
870.2400	Primary Eye Irritation: Rabbit	44942006		OLD	
870.2500	Primary Dermal Irritation	44942007		OLD	
870.2600	Dermal Sensitization	44942008		OLD	
870.7200	Companion Animal Safety	Cite-All		PAY	
810.3300	Product Performance	Cite-All		PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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DATA MATRIX

Date Jan. 4, 2018	EPA Reg. No./File Symbol 91300-5	Page 4 of 14
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
US 16 CFR § 1700	Child Resistant Packaging Study	48703501	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48703502	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48703503	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48703504	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48652701	Horizon Valley Generics, Inc.	PER	
		49179701	TruProdigy	PER	
		49179702	TruProdigy	PER	
		49179703	TruProdigy	PER	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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DATA MATRIX

Date Jan. 4, 2018	EPA Reg. No./File Symbol 91300-5	Page 5 of 14
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
US 16 CFR § 1700	Child Resistant Packaging Study – Single Applicator	KVS/201522	Klocke Verpackungs-Service	PER	
		KVS/201521	Klocke Verpackungs-Service	PER	
		49794002	Klocke Verpackungs-Service	PER	
		49794001	Klocke Verpackungs-Service	PER	
		49719402	Klocke Verpackungs-Service	PER	
		49719401	Klocke Verpackungs-Service	PER	
		49649301	Klocke Verpackungs-Service	PER	
		49649302	Klocke Verpackungs-Service	PER	
		49649303	Klocke Verpackungs-Service	PER	
		49649304	Klocke Verpackungs-Service	PER	
		49649305	Klocke Verpackungs-Service	PER	
		49649306	Klocke Verpackungs-Service	PER	
		49649307	Klocke Verpackungs-Service	PER	
		49649308	Klocke Verpackungs-Service	PER	

Product-Specific Data Requirements

Promika, LLC will make offers-to-pay to the following companies on the Fipronil data submitters list of October 19, 2017.

	Cite-All	Syngenta Crop Protection, LLC	PAY	
	Cite-All	The Scotts Company	PAY	
	Cite-All	Bayer Cropscience LP	PAY	
	Cite-All	Bayer Environmental Science	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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DATA MATRIX

Date Jan. 4, 2018	EPA Reg. No./File Symbol 91300-5	Page 6 of 14
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	BASF Corp.	PAY	
		Cite-All	Zoetis, Inc.	PAY	
		Cite-All	McLaughlin Gormley King Co.	PAY	
		Cite-All	Virbac AH, Inc.	PAY	
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Vetoquinol USA	PAY	
		Cite-All	Reckitt Benckiser LLC	PAY	
		Cite-All	Cheminova A/S	PAY	
		Cite-All	J. J. Mauget Co.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	Chemsico	PAY	
		Cite-All	Sumitomo Chemical Co., Ltd.	PAY	
		Cite-All	Adama Makhteshim Ltd.	PAY	
		Cite-All	Gharda Chemicals Ltd.	PAY	
		Cite-All	Finchimica S.p.A.	PAY	
		Cite-All	Control Solutions, Inc.	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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DATA MATRIX

Date Jan. 4, 2018	EPA Reg. No./File Symbol 91300-5	Page 7 of 14
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Virbac	PAY	
		Cite-All	Combat Insect Control Systems	PAY	
		Cite-All	Nisus Corp.	PAY	
		Cite-All	Pyrethroid Working Group	PAY	
		Cite-All	Merial, Inc.	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Cheminova Inc.	PAY	
		Cite-All	Elanco US Inc.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Innovative Pest Control Products	PAY	
		Cite-All	FIFRA Endangered Species Task Force	PAY	
		Cite-All	Adama Irvita N.V.	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Klocke Verpackungs-Service Gmbh	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agricultural Handler Exposure Task Force	PAY	
		Cite-All	Ceva Animal Health LLC	PAY	
		Cite-All	Sharda USA LLC	PAY	
		Cite-All	Gharda Generics, Inc.	PAY	
		Cite-All	Fidopharm, Inc.	PAY	
		Cite-All	Norbrook Laboratories Limited	PAY	
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Linouvel, Inc.	PAY	
		Cite-All	Zhejiang Hisun Pharmaceuticals Co., Ltd.	PAY	
		Cite-All	Argite LLC	PAY	
		Cite-All	Argite – Fipronil LLC	PAY	
		Cite-All	Fipronex Solutions Inc.	PAY	
		Cite-All	Virbac S.A.	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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DATA MATRIX

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Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Raymat Materials, Inc.	PAY	
		Cite-All	Chanelle Pharmaceuticals Manufacturing	PAY	
		Cite-All	Horizon Valley Generics, Inc.	PAY	
		Cite-All	American Vet Sciences LLC	PAY	
		Cite-All	Prodigy Technical Holding, LLC	PAY	
		Cite-All	Tru Prodigy	PAY	
		Cite-All	TruRx LLC	PAY	
		Cite-All	Adela Monica Buljbasich	PAY	
		Cite-All	2 Star Solution Inc.	PAY	
		Cite-All	Fipronil Task Force LLC Pet Cluster	PAY	
		Cite-All	Fipronil Task Force LLC Non-crop Cluster	PAY	
		Cite-All	Fipronil Task Force LLC Crop Cluster	PAY	
		Cite-All	CAP Supply, Inc.	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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Date Jan. 4, 2018	EPA Reg. No./File Symbol 91300-5	Page 10 of 14
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Shanghai Neway Animal Health Co., Ltd.	PAY	
		Cite-All	TG Medwise, Ltd.	PAY	
		Cite-All	Tigris Environmental Science LLC	PAY	
		Cite-All	TEVRA Brands, LLC	PAY	
		Cite-All	PGPO, LLC	PAY	
Promika, LLC will make offers-to-pay to the following companies on the S-methoprene data submitters list of October 19, 2017.					
		Cite-All	The Scotts Company	PAY	
		Cite-All	ADM Animal Nutrition	PAY	
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Wellmark International	PAY	
		Cite-All	S. C. Johnson & Son Inc.	PAY	
		Cite-All	Nippon Soda Co., Ltd.	PAY	
		Cite-All	Clarke Mosquito Control Products Inc.	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Chattem, Inc.	PAY	
		Cite-All	Zep Commercial Sales & Service	PAY	
		Cite-All	Control Solutions, Inc.	PAY	
		Cite-All	Management Contract Services Inc.	PAY	
		Cite-All	Merial, Inc.	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	B2E Corp.	PAY	
		Cite-All	Babolna Bioenvironmental Centre Ltd.	PAY	
		Cite-All	Egis Pharmaceuticals Public Limited Co.	PAY	
		Cite-All	Valent Biosciences Corp.	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Hartz-B2E LLC	PAY	
		Cite-All	Klocke Verpackungs-Service GmbH	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	B2E Biotech LLC	PAY	
		Cite-All	Zocor Inc.	PAY	
		Cite-All	Ceva Animal Health LLC	PAY	
		Cite-All	Fidopharm, Inc.	PAY	
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Linouvel, Inc.	PAY	
		Cite-All	Envincio LLC	PAY	
		Cite-All	Raymat Materials Inc.	PAY	
		Cite-All	U.S. Animal Health	PAY	
		Cite-All	Horizon Valley Generics Inc.	PAY	
		Cite-All	Sequent Scientific Limited	PAY	
		Cite-All	Central Garden & Pet Co.	PAY	
		Cite-All	CAP Supply Inc.	PAY	
		Cite-All	Shanghai New Animal Health Co., Ltd.	PAY	
		Cite-All	TEVRA Brands, LLC	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	PGPO, LLC	PAY	
Generic Data Requirements					
Promika LLC's Promika ZoGuard Plus for Dogs qualifies for Formulator's Exemption for fipronil and S-methoprene generic data requirements.					

Signature 	Name and Title Ann M. Tillman, Consultant	Date Jan. 4, 2018
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Endnotes for Data Matrix for Promika ZoGuard Plus for Dogs

- ¹ **830.1650** - These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- ² 830.1800 – This report was submitted concurrent with the application for registration of Promika ZoGuard Plus for Cats.
- ³ **830.6314** – Promika, LLC requested a waiver from the requirement of this data requirement because this product is intended for use as an on-animal spot-on. During normal usage, it will not come into contact with any oxidizing or reducing agents. This product does not contain any oxidizing or reducing agents. Please refer to the Confidential Statement of Formula for Promika ZoGuard Plus for Dogs.
- ⁴ **830.6316** – Promika LLC requested a waiver from this data requirement because fipronil and (S)-methoprene do not have the chemical bonds or functional groups associated with explosive chemicals. There are no potentially explosive ingredients in Promika ZoGuard Plus for Dogs (refer to the CSF for Promika ZoGuard Plus for Dogs).
- ⁵ **830.6317, 830.6320** - Promika, LLC has initiated these studies and will submit the final report upon study completion.
- ⁶ **830.6319, 830.6321, 830.7520** – Promika ZoGuard Plus for Dogs is not an emulsifiable concentrate and its labeling does not allow it to be diluted with petroleum solvents; therefore miscibility data is not applicable to Promika ZoGuard Plus for Dogs. Promika ZoGuard Plus for Dogs is not to be applied around electrical equipment; therefore dielectric breakdown voltage data is not applicable. Promika, LLC requested a waiver from the requirement of particle size, fiber length, and diameter distribution because the product is not a fibrous material and is not a water-insoluble material.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM:

DP BARCODE No.: 442026

FILE SYMBOL No.: 91300-5

PRODUCT NAME: Promika Zoguard Plus for Dogs

DECISION No.: 532222

PC Code(s): 129121 & 105402

ACTION CODE: 300

Company Name: Promika, LLC

Active Ingredient(s): Fipronil, 9.8% & S-Methoprene, 8.8%

DATE OUT: 29 September 2017

SUBJECT: Child-Resistant Packaging Certification Review

FROM: Lindsay Roe
CRP Reviewer
Fungicide Branch, Registration Division

A handwritten signature in black ink, appearing to read "Lindsay Roe".

TO: Julie Breeden-Alemi
Risk Manager, RM Team 3
Invertebrate-Vertebrate Branch 1

CONCLUSION:

The child resistant packaging certification dated 08/04/2017 and submitted to add new, additional packaging for this product is acceptable. This certification adds a small single thermoforme applicator with a fill volume of 0.67 mL; a medium single thermoforme applicator with a fill volume of 1.34 mL; and large single thermoforme applicators with fill volumes of 1.34, 2.68, and 4.02 mL. This additional CRP is supported by MRIDs 49794001, 49794002, 49649308, 49719401, 49649301, 49649302, 49649303, 49649304, 49649306, 49649307, 49719402, and 49649305, which must be included on the data matrix for this product. These MRIDs include SAUE testing carried out on strips of three applicators, which can be bridged to a single applicator of the same design, manufacture, and fill volume. Please see certification attached to this review for additional information and opening instructions that must be included on the product label.

The child resistant packaging certification dated 09/29/2017 and submitted to add new, additional packaging for this product is acceptable. This certification adds small 3-strip and 4-strip thermoforme applicators with a fill volume of 0.67 mL; medium 3-strip and 4-strip thermoforme applicators with a fill volume of 1.34 mL; and large 3-strip and 4-strip thermoforme applicators with fill volumes of 1.34, 2.68, and 4.02 mL. This additional CRP is supported by MRIDs 49649302, 49649303, 49649306, 49649307, and 49649305, which must be included on the data matrix for this product. These MRIDs include SAUE testing conducted using strips of three applicators, which can be bridged to a 4-strip of the same design, manufacture, and fill volume. Multiple 3-and 4-strips as presented in this certification may be sold together as long as those strips themselves are not physically connected in any way. Please see certification attached to this review for additional information and opening instructions that must be included on the product label.

Child Resistant Packaging Certification on August 4, 2017
Promika ZoGuard Plus for Dogs, EPA File No. 91300-5

Registrant: Promika, LLC
501 Cascade Point Lane, Suite 102
Cary, NC 27513

Child resistant packaging certification for EPA Reg. No. 91300-5, Promika ZoGuard Plus for Dogs, is filled and packaged by Firma Klocke Verpackungs-Service GmbH (KVS). CRP is mandatory for this product. Certification is provided to support approval for a label amendment to add this CR package.

The package consists of a placebo filled applicator with a clear plastic front and white foil backing with black printing. The clear plastic front is constructed of CPA/PP/COC/HDPE - 50/100/380/50 µm and the lidding material for the applicator is PET/OPA/ALU/HDPE - 23/25/9/50 µm. KVS designed and developed a child-resistant package (Thermoforme Applicator) that consists of a single applicator. The applicator is the child-resistant packaging. This child-resistant package correlates to ASTM F 904.

The applicator bulb falls into three sizes – small, medium, and large. The overall size of the strip and fill volumes of the applicators are as follows:

1-count (referred to as “singles”): 36 mm x 77 mm. The small applicator fill volume is 0.67 mL

1-count: 36 mm x 77 mm. The medium applicator fill volume is 1.34 mL

1-count: 36 mm x 77 mm. The large applicator fill volume is 1.34, 2.68 and 4.02 mL

Retail Packaging: The individual retail carton of this product will contain one applicator.

To ensure CR integrity of the package, CRP testing was carried out on the CR applicator with applicators of various fill volumes: See summary table, below.

The firm that conducted the testing: National Child Resistant Testing, Inc., 1101 West Britt St., Lincoln, NE 68521. All studies were conducted according to the requirements of the packaging standards and testing procedures under 16 CFR 1700 (revised July 21, 1995) of the U.S. Consumer Product Safety Commission (CPSC) and is not subject to the Good Laboratory Practice regulations as set forth in 40 CFR 160.

I realize that additional Child Resistant Packaging (CRP) testing may be required if ZoGuard Plus for Dogs is not filled and packaged by KVS on the same equipment as the samples tested. Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for ZoGuard Plus for Dogs.

Directions for use for SAUE: see the Opening Instructions on the attached page.

Number of units that represents a child failure: one. See summary table below for number of units a child received at the beginning of the test.

CRP certification statement: I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32 including the revised standards in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20 as published in 60 FR 37710 (July 21, 1995).



Ann M. Tillman
Agent, Promika, LLC

Aug. 4, 2017
Date

CRE Results – CR is a Small Bulb, Single Applicator Filled with 0.67 mL

KVS (Germany) is including other CRE data for this small bulb CR package. The additional data are for different fill volume (0.23 mL) in this same package but prepared and filled at Klocke of America (KOA, Florida). The KOA samples were using the same tools, materials and conditions as used by KVS (Germany).

Package Description: Small Bulb, 1.0 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Single	0.23	1	3 (94%)	50	KOA-201601
Single	0.5	1	1 (98%)	50	KVS-201522: (49794001)
Single	0.67	1	1 (98%)	50	KVS-201701

CRP Results – CR is a Medium Bulb, Single Applicator Filled with 1.34 mL

Package Description: Small Bulb, 2.9 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Single	1.34	1	0 (100%)	50	KVS-201702

CRP Results – CR is a Large Bulb, Single Applicator Filled with 1.34, 2.68 and 4.02 mL

Package Description: Small Bulb, 5.0 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Single	1.34	1	1 (98%)	50	KVS-201703
Single	2.68	1	0 (100%)	50	KVS-201704
Single	4.02	1	0 (100%)	50	KVS-201523 (49794002)

SAUE Results – CR is a Small Bulb, Single Applicator Filled with 0.67 mL

Although KVS (Germany) did not conduct SAUE tests with this CR package (single applicator, small bulb filled with 0.67 mL), KVS conducted other studies that support this CR package. SAUE studies were carried out with the same CR package but with a different configuration, i.e., 3 applicators (triple) connected in a strip. In SAUE testing, Seniors are required to open only one unit in each test and KVS requests these data be used to bridge to the small bulb, single-count applicator filled with 0.67 mL.

Other SAUE data in support of this CR package include studies with the KVS triples and quads filled with other volumes (0.23 mL and 0.5 mL). In addition, data are provided for singles (0.23 mL) and triples (1.0 mL) prepared and filled at Klocke of America (KOA, Florida). The KOA packages for testing were prepared using the same tools, materials and conditions as used by KVS (Germany).

Package Description: Small Bulb, 1.0 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Single	0.23	0 (100%)	KOA-201601
Triple (3 strips of 3 applicators)	0.23	4 (96%)	KVS-201508 (49649308)
Quad (1 strip of 4 applicators)	0.23	7 (93%)	KVS-201517; (49719401)
Triple (1 strip of 3 applicators)	0.5	0 (100%)	KVS-201501; (49649301)
Triple (1 strip of 3 applicators)	0.67	2 (98%)	KVS-201502; (49649302)
Triple (1 strip of 3 applicators)	1.0	1 (99%)	KOA-201701

SAUE Results – CR is a Medium Bulb, Single Applicator Filled with 1.34 mL

Although KVS (Germany) did not conduct SAUE tests with this CR package (single applicator, medium bulb filled with 1.34 mL), KVS conducted other studies that support this CR package. SAUE studies were carried out with the same CR package filled with 1.34 mL but with a different configuration, i.e., 3 applicators (triple) connected in a strip. In SAUE testing, seniors are required to open only one unit in each test and KVS requests these data be used to bridge to the medium bulb, single-count applicator filled with 1.34 mL.

KVS (Germany) is including other SAUE data in support of this CR package. The additional data are from SAUE studies of the KVS package filled with 2.68 mL in a different configuration, i.e., 3 applicators connected in a strip (triple). In SAUE testing, seniors are required to open only one unit in each test.

Package Description: Small Bulb, 2.9 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Triple (1 strip of 3 applicators)	1.34	3 (97%)	KVS-201503 (49649303)
Triple (1 strip of 3 applicators)	2.68	1 (99%)	KVS-201504 (49649304)

SAUE Results – CR is a Large Bulb, Single Applicator Filled with 1.34, 2.68, and 4.02 mL

Although KVS (Germany) did not conduct SAUE tests with this CR package (single applicator, large bulb filled with 1.34, 2.68 and 4.02 mL), KVS (Germany) would like to bridge data to this CR package from SAUE data generated with the same package and large bulb size filled with between 1.34 mL and 4.02 mL but with different configurations, i.e., 3 or 4 applicators connected in a strip (triples, quads). In SAUE testing, Seniors are required to open only one unit in each test.

KVS (Germany) is including other SAUE data in support of this CR package. The additional data are for a different fill volume (5.0 mL) and for the same package prepared at Klocke of America (KOA, Florida). The KOA packages for testing were prepared using the same tools, materials and conditions as used by KVS (Germany).

Package Description: Small Bulb, 5.0 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Triple (1 strip of 3 applicators)	1.34	2 (98%)	KVS-201506 (49649306)
Triple (1 strip of 3 applicators)	2.68	1 (99%)	KVS-201507 (49649307)
Quad (1 strip of 4 applicators)	4.0	1 (99%)	KVS-201518 (49719402)
Triple (1 strip of 3 applicators)	4.02	3 (97%)	KVS-201505 (49649305)
Quad (1 strip of 4 applicators)	5.0	2 (98%)	KOA-201702

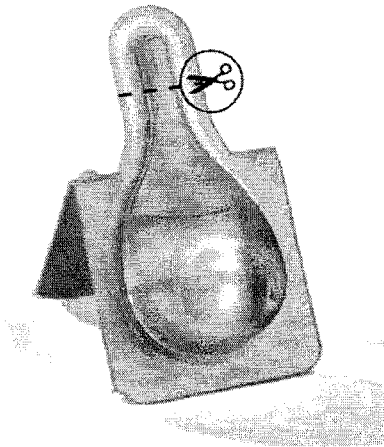
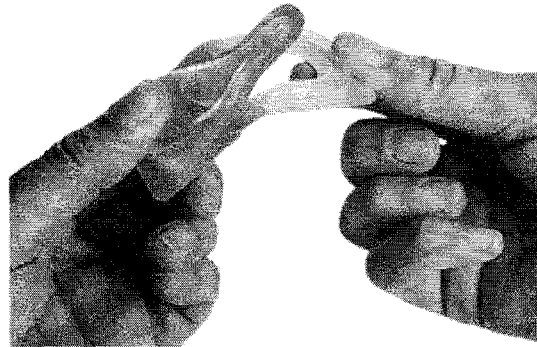
NOTE: EPA previously approved the single small bulb with fill volume of 0.5 mL. Ref. EPA Memorandum dated July 13, 2016 from Lisa Pahel to Jennifer Gaines and Bo Davis (DP Barcode 434001; MRID 49719401, 49719402, 49719403, 49794001). These data were also considered by the Agency and found acceptable for this CR (single applicators containing fill volumes between 0.4mL and 4.0 mL for EPA Reg. No. 91384-3).

Children used in testing: 42-51 months old, broken into three age groups (30%, 42-44 months; 40%, 45-48 months; 30%, 49-51 months). Gender breakdown of 50% female and 50% male with a 10% difference allowed in each age category.)

Seniors used in testing: 50-70 years old, broken into three age groups (25%, 50-54 years; 25%, 55-59 years; 50%, 60-70 years). Gender breakdown of 70% female and 30% male in each group

PACKAGE OPENING INSTRUCTIONS FOR SAUE (SIZE OF OI BELOW IS SAME AS USED IN TESTING)

1 Fold back the safety tab



2 Cut with scissors to open applicator

**Child Resistant Packaging Certification on September 29, 2017
ZoGuard Plus for Dogs, EPA File No. 91300-5**

Registrant: **Promika, LLC**
501 Cascade Point Lane, Suite 102
Cary, NC 27513

Child resistant packaging certification for EPA Reg. No. 91300-5, ZoGuard Plus for Dogs, is filled and packaged by Klocke of America (KOA), 14201 Jetport Loop, Fort Myers, FL 33913. CRP is mandatory for this product. Certification is provided to support approval for a label amendment to add this CR package.

The package consists of a placebo filled applicator with a clear plastic front and white foil backing with black printing. The clear plastic front material is constructed of CPA/PP/COC/HDPE - 50/100/380/50 µm and the lidding material for the applicator is PET/OPA/ALU/HDPE - 23/25/9/50 µm. The child-resistant package (Thermoforme Applicator) consists of three or four applicators connected to each other in one strip. There is a perforation between each unit so that a single applicator may be removed from the other units. The applicator is the child-resistant packaging. This child-resistant package correlates to ASTM F 904.

The applicator bulb falls into three sizes – small, medium and large. The applicator fill volumes are 0.67 mL (small bulb), 1.34 mL (medium and large bulb), 2.68 (large bulb) and 4.02 mL (large bulb). The overall sizes of the strips are as follows:

3-count (referred to as “triples”): 108 mm x 77 mm
6-count: 2 x 108 mm x 77 mm
12-count: 4 x 108 mm x 77 mm
4-count (referred to as “quads”): 144 mm x 77 mm
8-count: 2 x 144 mm x 77 mm
12-count: 3 x 144 mm x 77 mm

Retail Packaging: The individual retail carton of this product will contain either one strip of 3 applicators (triples), two strips of 3 applicators, four strips of 3 applicators, one strip of 4 applicators (quads), two strips of 4 applicators, or three strips of 4 applicators.

To ensure CR integrity of the package, CRP testing was carried out on the CR applicator with applicators of various fill volumes: See summary table, below.

The firm that conducted the testing: National Child Resistant Testing, Inc., 1101 West Britt St., Lincoln, NE 68521. All studies were conducted according to the requirements of the packaging standards and testing procedures under 16 CFR 1700 (revised July 21, 1995) of the U.S. Consumer Product Safety Commission (CPSC) and is not subject to the Good Laboratory Practice regulations as set forth in 40 CFR 160.

I realize that additional Child Resistant Packaging (CRP) testing may be required if ZoGuard Plus for Dogs is not filled and packaged by KOA on the same equipment as the samples tested. Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for ZoGuard Plus for Dogs.

Directions for use for SAUE: see the Opening Instructions on the attached page.

Number of units that represents a child failure: one. See summary table below for number of units a child received at the beginning of the test.

CRP certification statement: I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32 including the revised standards in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20 as published in 60 FR 37710 (July 21, 1995).



Ann M. Tillman
Agent, Promika, LLC

Sept. 29, 2017
Date

CRE Results – Small Bulb (0.67 mL)

KOA would like to bridge data for this CR package (small bulb, triples and quads containing 0.67 mL) from CRE studies conducted with this same package prepared at KVS (Germany) since the packages for testing were prepared using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 1.0 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Triple	0.67	3	4 (92%)	50	KVS-201502 (49649302)

CRE Results – Medium Bulb (1.34 mL)

KOA would like to bridge data for this CR package (medium bulb, triples and quads containing 1.34 mL) from CRE studies conducted with this same package prepared at KVS (Germany) since the packages for testing were prepared using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 2.9 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Triple	1.34	3	3 (94%)	50	KVS-201503 (49649303)

CRE Results – Large Bulb (1.34, 2.68 and 4.02 mL)

KOA would like to bridge data for this CR package (large bulb, triples and quads containing 1.34 mL, 2.68 mL and 4.02 mL) from CRE studies conducted with this same package prepared at KVS (Germany) since the packages for testing were prepared using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 5.0 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Triple	1.34	3	2 (96%)	50	KVS-201506 (49649306)
Triple	2.68	3	2 (96%)	50	KVS-201507 (49649307)
Triple	4.02	3	2 (96%)	50	KVS-201505 (49649305)

Note: The proposal for bridging data from KVS samples to KOA was agreed upon by EPA based on a meeting between EPA (Lisa Pahel and Lindsey Roe) and KOA on April 19, 2017.

SAUE Results – Small Bulb (0.67 mL)

KOA would like to bridge data to this CR package (the small bulb, triples and quads, containing 0.67 mL) from SAUE data generated with this same package prepared at KVS (Germany) since the packages for testing were prepared using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 1.0 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Triple	0.67	2 (98%)	KVS-201502; (49649302)

SAUE Results – Medium Bulb (1.34 mL)

KVS would like to bridge data to this CR package (medium bulb, triples and quads, containing 1.34 mL) from SAUE data generated with this same package prepared at KVS (Germany) since the packages for testing were prepared using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 2.9 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Triple	1.34	3 (97%)	KVS-201503 (49649303)

SAUE Results – Large Bulb (1.34, 2.68 and 4.02 mL)

KVS would like to bridge data for this CR package (large bulb, triples and quads, containing 1.34, 2.68 and 4.02 mL) from SAUE studies conducted with this same package prepared at KVS (Germany) since the packages for testing were prepared using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 5.0 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Triple (1 strip of 3 applicators)	1.34	2 (98%)	KVS-201506 (49649306)
Triple (1 strip of 3 applicators)	2.68	1 (99%)	KVS-201507 (49649307)
Triple (1 strip of 3 applicators)	4.02	3 (97%)	KVS-201505 (49649305)

Note: The proposal for bridging data from KVS samples to KOA was agreed upon by EPA based on a meeting between EPA (Lisa Pahel and Lindsey Roe) and KOA on April 19, 2017.

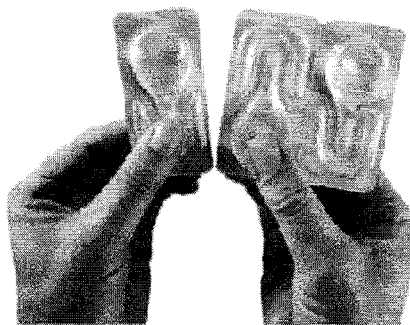
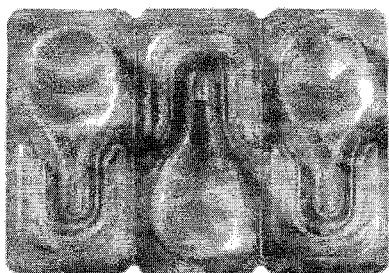
Children used in testing: 42-51 months old, broken into three age groups (30%, 42-44 months; 40%, 45-48 months; 30%, 49-51 months). Gender breakdown of 50% female and 50% male with a 10% difference allowed in each age category).

Seniors used in testing: 50-70 years old, broken into three age groups (25%, 50-54 years; 25%, 55-59 years; 50%, 60-70 years). Gender breakdown of 70% female and 30% male in each group.

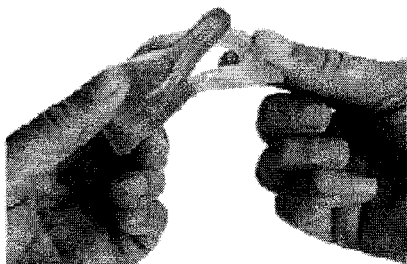
NOTE: EPA previously approved the CRP manufactured at KVS (Germany) for one strip of 3 units (triples) with fill volumes ranging from 0.5 mL to 4.02 mL as well as two strips of 3 units. Ref.: Memorandum dated November 18, 2015 from Maggie Rudick to Tim Ciarlo and Bo Davis (MRID 49649301) and Memorandum dated November 18, 2015 from Maggie Rudick to Tim Ciarlo and Bo Davis (MRID 49649302, 49649303, 49649304, 49649305, 49649306, and 49649307). The two strips of 3 units (triples) were approved based on bridging of data from one strip of 3 units. EPA also agreed to bridge data from triples to quads.

PACKAGE OPENING INSTRUCTIONS FOR SAUE – TRIPLES AND QUADS

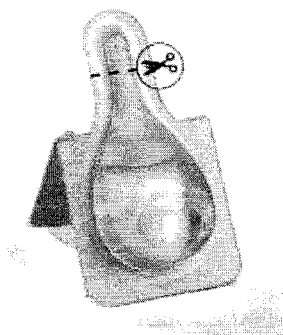
1 Tear through perforation



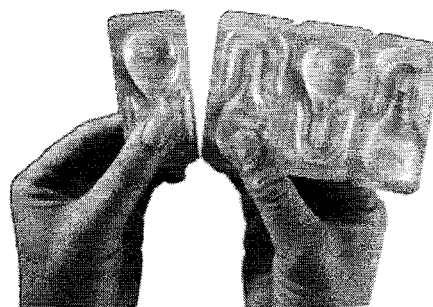
2 Fold back the safety tab



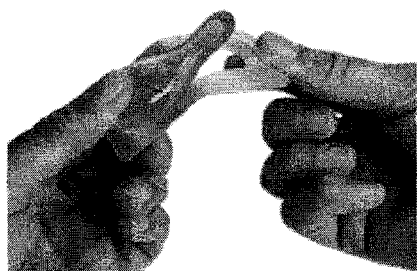
3 Cut with scissors to open applicator



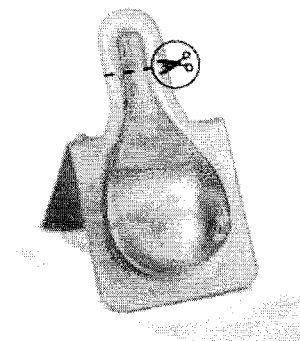
1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator



Child Resistant Packaging Certification on August 4, 2017
Promika ZoGuard Plus for Dogs, EPA File No. 91300-5

Registrant: **Promika, LLC**
 501 Cascade Point Lane, Suite 102
 Cary, NC 27513

Child resistant packaging certification for EPA Reg. No. 91300-5, Promika ZoGuard Plus for Dogs, is filled and packaged by Firma Klocke Verpackungs-Service GmbH (KVS). CRP is mandatory for this product. Certification is provided to support approval for a label amendment to add this CR package.

The package consists of a placebo filled applicator with a clear plastic front and white foil backing with black printing. The clear plastic front is constructed of CPA/CPP/COC/HDPE - 50/100/380/50 µm and the lidding material for the applicator is PET/OPA/ALU/HDPE - 23/25/9/50 µm. KVS designed and developed a child-resistant package (Thermoforme Applicator) that consists of a single applicator. The applicator is the child-resistant packaging. This child-resistant package correlates to ASTM F 904.

The applicator bulb falls into three sizes – small, medium, and large. The overall size of the strip and fill volumes of the applicators are as follows:

1-count (referred to as “singles”): 36 mm x 77 mm. The small applicator fill volume is 0.67 mL

1-count: 36 mm x 77 mm. The medium applicator fill volume is 1.34 mL

1-count: 36 mm x 77 mm. The large applicator fill volume is 1.34, 2.68 and 4.02 mL

Retail Packaging: The individual retail carton of this product will contain one applicator.

To ensure CR integrity of the package, CRP testing was carried out on the CR applicator with applicators of various fill volumes: See summary table, below.


The firm that conducted the testing: National Child Resistant Testing, Inc., 1101 West Britt St., Lincoln, NE 68521. All studies were conducted according to the requirements of the packaging standards and testing procedures under 16 CFR 1700 (revised July 21, 1995) of the U.S. Consumer Product Safety Commission (CPSC) and is not subject to the Good Laboratory Practice regulations as set forth in 40 CFR 160.

I realize that additional Child Resistant Packaging (CRP) testing may be required if ZoGuard Plus for Dogs is not filled and packaged by KVS on the same equipment as the samples tested. Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for ZoGuard Plus for Dogs:

Directions for use for SAUE: see the Opening Instructions on the attached page.

Number of units that represents a child failure: one. See summary table below for number of units a child received at the beginning of the test.

CRP certification statement: I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32 including the revised standards in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20 as published in 60 FR 37710 (July 21, 1995).



Ann M. Tillman
Agent, Promika, LLC

Aug. 4, 2017
Date

CRE Results – CR is a Small Bulb, Single Applicator Filled with 0.67 mL

KVS (Germany) is including other CRE data for this small bulb CR package. The additional data are for different fill volume (0.23 mL) in this same package but prepared and filled at Klocke of America (KOA, Florida). The KOA samples were using the same tools, materials and conditions as used by KVS (Germany).

Package Description: Small Bulb, 1.0 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Single	0.23	1	3 (94%)	50	KOA-201601
Single	0.5	1	1 (98%)	50	KVS-201522; (49794001)
Single	0.67	1	1 (98%)	50	KVS-201701

CRP Results – CR is a Medium Bulb, Single Applicator Filled with 1.34 ml

Package Description: Small Bulb, 2.9 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Single	1.34	1	0 (100%)	50	KVS-201702

CRP Results – CR is a Large Bulb, Single Applicator Filled with 1.34, 2.68 and 4.02 mL

Package Description: Small Bulb, 5.0 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Single	1.34	1	1 (98%)	50	KVS-201703
Single	2.68	1	0 (100%)	50	KVS-201704
Single	4.02	1	0 (100%)	50	KVS-201523 (49794002)

SAUE Results – CR is a Small Bulb, Single Applicator Filled with 0.67 mL

Although KVS (Germany) did not conduct SAUE tests with this CR package (single applicator, small bulb filled with 0.67 mL), KVS conducted other studies that support this CR package. SAUE studies were carried out with the same CR package but with a different configuration, i.e., 3 applicators (triple) connected in a strip. In SAUE testing, Seniors are required to open only one unit in each test and KVS requests these data be used to bridge to the small bulb, single-count applicator filled with 0.67 mL.

Other SAUE data in support of this CR package include studies with the KVS triples and quads filled with other volumes (0.23 mL and 0.5 mL). In addition, data are provided for singles (0.23 mL) and triples (1.0 mL) prepared and filled at Klocke of America (KOA, Florida). The KOA packages for testing were prepared using the same tools, materials and conditions as used by KVS (Germany).

Package Description: Small Bulb, 1.0 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Single	0.23	0 (100%)	KOA-201601
Triple (3 strips of 3 applicators)	0.23	4 (96%)	KVS-201508 (49649308)
Quad (1 strip of 4 applicators)	0.23	7 (93%)	KVS-201517; (49719401)
Triple (1 strip of 3 applicators)	0.5	0 (100%)	KVS-201501; (49649301)
Triple (1 strip of 3 applicators)	0.67	2 (98%)	KVS-201502; (49649302)
Triple (1 strip of 3 applicators)	1.0	1 (99%)	KOA-201701

SAUE Results – CR is a Medium Bulb, Single Applicator Filled with 1.34 mL

Although KVS (Germany) did not conduct SAUE tests with this CR package (single applicator, medium bulb filled with 1.34 mL), KVS conducted other studies that support this CR package. SAUE studies were carried out with the same CR package filled with 1.34 mL but with a different configuration, i.e., 3 applicators (triple) connected in a strip. In SAUE testing, seniors are required to open only one unit in each test and KVS requests these data be used to bridge to the medium bulb, single-count applicator filled with 1.34 mL.

KVS (Germany) is including other SAUE data in support of this CR package. The additional data are from SAUE studies of the KVS package filled with 2.68 mL in a different configuration, i.e., 3 applicators connected in a strip (triple). In SAUE testing, seniors are required to open only one unit in each test.

Package Description: Small Bulb, 2.9 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Triple (1 strip of 3 applicators)	1.34	3 (97%)	KVS-201503 (49649303)
Triple (1 strip of 3 applicators)	2.68	1 (99%)	KVS-201504 (49649304)

SAUE Results – CR is a Large Bulb, Single Applicator Filled with 1.34, 2.68, and 4.02 mL

Although KVS (Germany) did not conduct SAUE tests with this CR package (single applicator, large bulb filled with 1.34, 2.68 and 4.02 mL), KVS (Germany) would like to bridge data to this CR package from SAUE data generated with the same package and large bulb size filled with between 1.34 mL and 4.02 mL but with different configurations, i.e., 3 or 4 applicators connected in a strip (triples, quads). In SAUE testing, Seniors are required to open only one unit in each test.

KVS (Germany) is including other SAUE data in support of this CR package. The additional data are for a different fill volume (5.0 mL) and for the same package prepared at Klocke of America (KOA, Florida). The KOA packages for testing were prepared using the same tools, materials and conditions as used by KVS (Germany).

Package Description: Small Bulb, 5.0 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Triple (1 strip of 3 applicators)	1.34	2 (98%)	KVS-201506 (49649306)
Triple (1 strip of 3 applicators)	2.68	1 (99%)	KVS-201507 (49649307)
Quad (1 strip of 4 applicators)	4.0	1 (99%)	KVS-201518 (49719402)
Triple (1 strip of 3 applicators)	4.02	3 (97%)	KVS-201505 (49649305)
Quad (1 strip of 4 applicators)	5.0	2 (98%)	KOA-201702

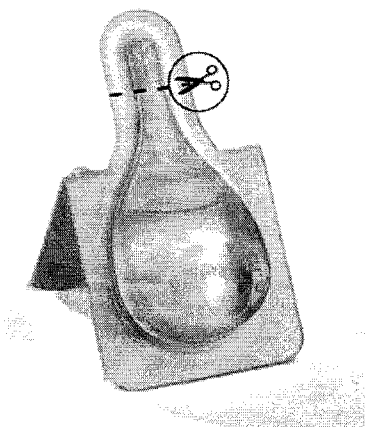
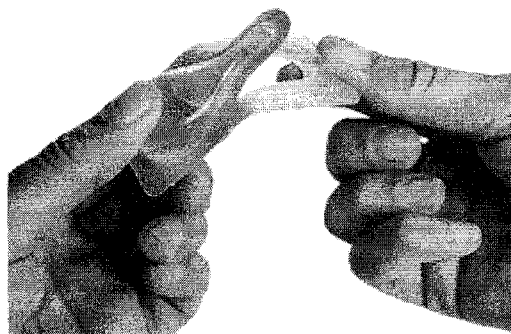
NOTE: EPA previously approved the single small bulb with fill volume of 0.5 mL. Ref. EPA Memorandum dated July 13, 2016 from Lisa Pahel to Jennifer Gaines and Bo Davis (DP Barcode 434001; MRID 49719401, 49719402, 49719403, 49794001). These data were also considered by the Agency and found acceptable for this CR (single applicators containing fill volumes between 0.4 mL and 4.0 mL for EPA Reg. No. 91384-3).

Children used in testing: 42-51 months old, broken into three age groups (30%, 42-44 months; 40%, 45-48 months; 30%, 49-51 months). Gender breakdown of 50% female and 50% male with a 10% difference allowed in each age category.)

Seniors used in testing: 50-70 years old, broken into three age groups (25%, 50-54 years; 25%, 55-59 years; 50%, 60-70 years). Gender breakdown of 70% female and 30% male in each group

PACKAGE OPENING INSTRUCTIONS FOR SAUE (SIZE OF OI BELOW IS SAME AS USED IN TESTING)

1 Fold back the safety tab



2 Cut with scissors to open applicator

**Child Resistant Packaging Certification on August 4, 2017
ZoGuard Plus for Dogs, EPA File No. 91300-5**

Registrant: **Promika, LLC**
 501 Cascade Point Lane, Suite 102
 Cary, NC 27513

Child resistant packaging certification for EPA Reg. No. 91300-5, ZoGuard Plus for Dogs, is filled and packaged by Klocke of America (KOA), 14201 Jetport Loop, Fort Myers, FL 33913. CRP is mandatory for this product. Certification is provided to support approval for a label amendment to add this CR package.

The package consists of a placebo filled applicator with a clear plastic front and white foil backing with black printing. The clear plastic front material is constructed of CPA/PP/COC/HDPE - 50/100/380/50 µm and the lidding material for the applicator is PET/OPA/ALU/HDPE - 23/25/9/50 µm. The child-resistant package (Thermoforme Applicator) consists of three or four applicators connected to each other in one strip. There is a perforation between each unit so that a single applicator may be removed from the other two units. The applicator is the child-resistant packaging. This child-resistant package correlates to ASTM F 904.

The applicator bulb falls into three sizes – small, medium and large. The applicator fill volumes are 0.67 mL (small bulb), 1.34 mL (medium and large bulb), 2.68 (large bulb) and 4.02 mL (large bulb). The overall sizes of the strips are as follows:

3-count (referred to as “triples”): 108 mm x 77 mm
6-count: 2 x 108 mm x 77 mm
12-count: 4 x 108 mm x 77 mm
4-count (referred to as “quads”): 144 mm x 77 mm
8-count: 2 x 144 mm x 77 mm
12-count: 3 x 144 mm x 77 mm

Retail Packaging: The individual retail carton of this product will contain either one strip of 3 applicators (triples), two strips of 3 applicators, four strips of 3 applicators, one strip of 4 applicators (quads), two strips of 4 applicators, or three strips of 4 applicators.

To ensure CR integrity of the package, CRP testing was carried out on the CR applicator with applicators of various fill volumes: See summary table, below.


The firm that conducted the testing: National Child Resistant Testing, Inc., 1101 West Britt St., Lincoln, NE 68521. All studies were conducted according to the requirements of the packaging standards and testing procedures under 16 CFR 1700 (revised July 21, 1995) of the U.S. Consumer Product Safety Commission (CPSC) and is not subject to the Good Laboratory Practice regulations as set forth in 40 CFR 160.

I realize that additional Child Resistant Packaging (CRP) testing may be required if ZoGuard Plus for Dogs is not filled and packaged by KVS or KOA on the same equipment as the samples tested. Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for ZoGuard Plus for Dogs.

Directions for use for SAUE: see the Opening Instructions on the attached page.

Number of units that represents a child failure: one. See summary table below for number of units a child received at the beginning of the test.

CRP certification statement: I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32 including the revised standards in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20 as published in 60 FR 37710 (July 21, 1995).



Ann M. Tillman
Agent, Promika, LLC

Aug. 4, 2017
Date

CRE Results – CR is a Small Bulb, Triple and Quad Applicator Filled with 0.67 mL

KOA would like to bridge data for this CR package (small bulb, triples and quads containing 0.67 mL) from CRE studies conducted with this same package prepared at KVS (Germany) since the packages for testing were prepared and filled at KVS using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 1.0 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Triple	0.23	3	4 (92%)	50	KOA-201603
Quad	0.23	3	4 (92%)	50	KOA-201605
Quad	0.23	4	4 (92%)	50	KVS-201517 (49719401)
Triple	0.5	3	3 (94%)	50	KVS-201501 (49649301)
Triple	0.67	3	4 (92%)	50	KVS-201502 (49649302)

CRE Results – CR is a Medium Bulb, Triple and Quad Applicator Filled with 1.34 ml

KOA would like to bridge data for this CR package (medium bulb, triples and quads containing 1.34 mL) from CRE studies conducted with this same package prepared at KVS (Germany) since the packages for testing were prepared and filled at KVS using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 2.9 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Triple	1.34	3	3 (94%)	50	KVS-201503 (49649303)
Triple	2.68	3	3 (94%)	50	KVS-201504 (49649304)
Triple	2.5	3	0 (100%)	50	KVS-201510 (49649310)

CRE Results – CR is a Large Bulb, Triple and Quad Applicator Filled with 1.34, 2.68 and 4.02 mL)

KOA would like to bridge data for this CR package (large bulb, triples and quads containing 1.34 mL, 2.68 mL and 4.02 mL) from CRE studies conducted with this same package prepared at KVS (Germany) since the packages for testing were prepared and filled at KVS using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 5.0 mL max. fill volume	Test Fill Volume, mL	Number of Units given to children	Number of children that opened/accessed contents in full 10 minutes (% child effectiveness)	Total number of children tested	Report No. (MRID)
Triple	1.34	3	2 (96%)	50	KVS-201506 (49649306)
Triple	2.68	3	2 (96%)	50	KVS-201507 (49649307)
Triple	4.0	3	4 (92%)	50	KVS-201515 (49681402)
Quad	4.0	3	1 (99%)	50	KVS-201518 (49719402)
Triple	4.02	3	2 (96%)	50	KVS-201505 (49649305)
Quad	5.0	3	5 (90%)	50	KOA-201606

Note: The proposal for bridging data from KVS samples to KOA was agreed upon by EPA based on a meeting between EPA (Lisa Pahel and Lindsey Roe) and KOA on April 19, 2017.

SAUE Results – CR is a Small Bulb, Triple and Quad Applicator Filled with 0.67 m

KOA would like to bridge data to this CR package (the small bulb, triples and quads, containing 0.67 mL) from SAUE data generated with this same package prepared at KVS (Germany) since the packages for testing were prepared and filled at KVS using the same tools, materials and conditions as used by KOA. See Note below.

Other SAUE data support this CR package (small bulb, triples and quads containing 0.67 mL) including data for this same package prepared and filled at Klocke of America (KOA, Florida) with fill volumes 0.23 mL and 1.0 mL. The KOA packages for testing were prepared using the same tools, materials and conditions as used by KVS (Germany).

Package Description: Small Bulb, 1.0 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Single	0.23	0 (100%)	KOA-201601
Triple (3 strips of 3 applicators)	0.23	4 (96%)	KVS-201508 (49649308)
Quad	0.23	7 (93%)	KVS-201517; (49719401)
Triple	0.5	0 (100%)	KVS-201501; (49649301)
Triple	0.67	2 (98%)	KVS-201502; (49649302)
Triple	1.0	1 (99%)	KOA-201701

SAUE Results – CR is a Medium Bulb, Triple and Quad Applicator Filled with 1.34 ml

KVS would like to bridge data to this CR package (medium bulb, triples and quads, containing 1.34 mL) from SAUE data generated with this same package prepared at KVS (Germany) since the packages for testing were prepared and filled using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 2.9 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Triple	1.34	3 (94%)	KVS-201503 (49649303)
Triple	2.68	3 (94%)	KVS-201504 (49649304)

SAUE Results – CR is a Large Bulb, Triple and Quad Applicator Filled with 1.34, 2.68 and 4.02 mL

KVS would like to bridge data for this CR package (large bulb, triples and quads, containing 1.34, 2.68 and 4.02 mL) from SAUE studies conducted with this same package prepared at KVS (Germany) since the packages for testing were prepared and filled using the same tools, materials and conditions as used by KOA. See Note below.

Package Description: Small Bulb, 5.0 mL max. fill volume	Test Fill Volume, mL	Number of Failures (% senior effectiveness)	KVS Report No. (MRID)
Triple (1 strip of 3 applicators)	1.34	2 (98%)	KVS-201506 (49649306)
Triple (1 strip of 3 applicators)	2.68	1 (99%)	KVS-201507 (49649307)
Quad (1 strip of 4 applicators)	4.0	1 (99%)	KVS-201518 (49719402)
Triple (1 strip of 3 applicators)	4.02	3 (97%)	KVS-201505 (49649305)
Quad (1 strip of 4 applicators)	5.0	2 (98%)	KOA-201702

Note: The proposal for bridging data from KVS samples to KOA was agreed upon by EPA based on a meeting between EPA (Lisa Pahel and Lindsey Roe) and KOA on April 19, 2017.

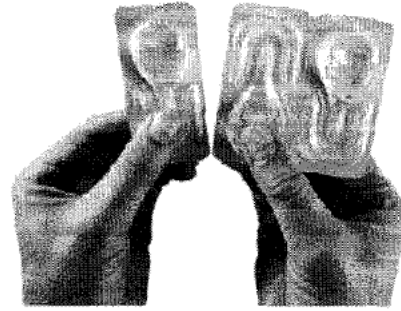
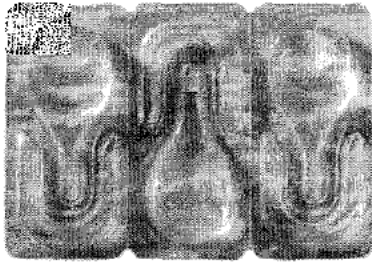
EPA previously approved the CRP manufactured at KVS (Germany) for one strip of 3 units (triples) with fill volumes ranging from 0.5 mL to 4.02 mL as well as two strips of 3 units. Ref.: Memorandum dated November 18, 2015 from Maggie Rudick to Tim Ciarlo and Bo Davis (MRID 49649301) and Memorandum dated November 18, 2015 from Maggie Rudick to Tim Ciarlo and Bo Davis (MRID 49649302, 49649303, 49649304, 49649305, 49649306, and 49649307). The two strips of 3 units (triples) were approved based on bridging of data from one strip of 3 units. EPA also agreed to bridge data from triples to quads.

Children used in testing: 42-51 months old, broken into three age groups (30%, 42-44 months; 40%, 45-48 months; 30%, 49-51 months). Gender breakdown of 50% female and 50% male with a 10% difference allowed in each age category).

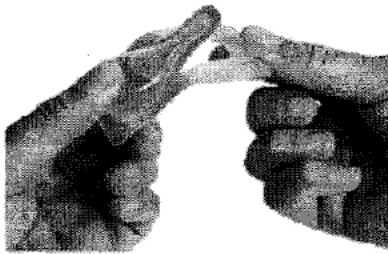
Seniors used in testing: 50-70 years old, broken into three age groups (25%, 50-54 years; 25%, 55-59 years; 50%, 60-70 years). Gender breakdown of 70% female and 30% male in each group.

PACKAGE OPENING INSTRUCTIONS FOR SAUE – TRIPLES AND QUADS

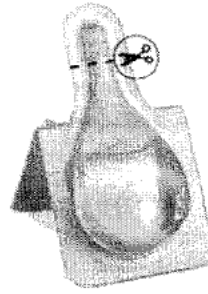
1 Tear through perforation



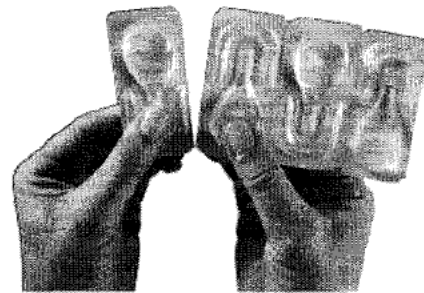
2 Fold back the safety tab



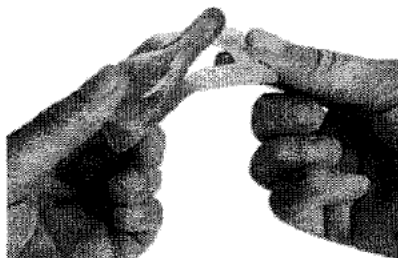
3 Cut with scissors to open applicator



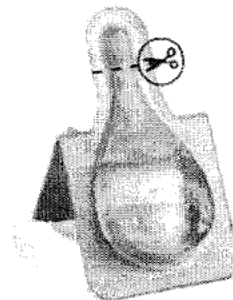
1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator



 Environmental Protection Agency United States Washington, DC 20460	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number _____
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Application for Pesticide – Section I

1. Company/Product Number Promika LLC/91300-5	2. EPA Product Manager Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Promika, LLC/Promika ZoGuard Plus for Dogs	PM# 3	
5. Name and Address of Applicant (include ZIP Code) Promika, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
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Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Label amendment to add alternate packaging.

If you should have any questions concerning this submission, please contact me by e-mail at Ann@PyxisRC.com or by phone at (253) 853-7369.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136 fl. oz	No. per container 1,3,6, 12	If "Yes" Package wgt. _____	No. per container _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1, 3, 4, 6, 8, 12 x 0.023, 0.045, 0.091, 0.136 fl oz		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other on box and insert <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date Aug. 04, 2017	



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
F: (253) 853-5516
ANN@PYXISRC.COM

August 4, 2017

ELECTRONIC SUBMISSION

Kable (Bo) Davis (PM 3)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Promika, LLC
Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5)
Non-PRIA Fast Track Amendment to Add Additional Packaging Options

Dear Mr. Davis,

On behalf of Promika, LLC, we are submitting a fast-track amendment to amend the label for Promika ZoGuard Plus for Dogs to add Child Resistant Packaging (CRP) in three different retail package options and to update the current Sublabel 1 has been updated to reflect current EPA guidelines for spot-on product labels.

The currently approved label (now Sublabel 1) allows packaging of the following child resistant (CR) applicators manufactured and filled by Klocke Verpackungs-Service in Germany (KVS) in one carton:

- One, two or three strips of three (3-count or triple) Child Resistant (CR) applicators

The first new retail package will consist of the same CR applicators manufactured and filled by KVS. The retail package options will be:

1. One Child Resistant (CR) applicator (single)

The labeling for option 1 is found in Sublabel 2. CRP data to support the single CR applicators were generated from samples manufactured at KVS. Promika, LLC is requesting to bridge SAUE CRP data generated from other studies using different configurations (triples, quads) since seniors are required to open only one applicator (unit) in each test. The bridging proposal and the summarized data are found in the enclosed CRP Certification.

The second two retail packages will consist of the same CR applicators (triples, quads) but the CRP will be manufactured and filled by Klocke of America in Fort Meyers, FL (KOA). The retail package options will be:

2. One, two or four strips of 3 Child Resistant (3-count or triple) applicators per carton
3. One, two or three strips of 4 Child Resistant applicators (4-count or quad) per carton

The labeling for options 2 and 3 is found in Sublabel 1. CRP data to support the 3-count and 4-count CR applicators were generated from samples manufactured at both KOA and KVS and the data is summarized in the enclosed CRP Certification. Promika, LLC is requesting to bridge CRP data generated from the same CR applicators made at KVS to the CRP data from CR applicators manufactured at KOA. The CR applicators made and filled by KOA were prepared using the same tools, materials and conditions as used by KVS. This bridging proposal and additional CRP testing of the applicators made and filled by KOA has been discussed in detail at a meeting between the manufacturer and the Agency (Lindsay Roe and Lisa Pahel) on April 19, 2017 and is detailed on the enclosed CRP Certifications.

Most of the CRP data to support these package options has been reviewed and approved by the Agency for other registered products¹. References to previously submitted CRP data and new data are found on the CRP Certifications. All CRP final reports which have not been formally submitted to the Agency are available for submission upon request.

In support of this application, we submit the following documents:

1. Application for Amended Pesticide Registration (EPA Form 8570-1)
2. One (1) copy of the Promika ZoGuard Plus for Cats label with changes tracked
3. One (1) copy of the Promika ZoGuard Plus for Cats label with changes incorporated
4. Child Resistant Packaging Certification for 3-count and 4-count for KOA
5. Child Resistant Packaging Certification for 1-count for KVS
6. Letter of Authorization

This action does not require review of data and, therefore, Promika, LLC believes that this amendment is not subject to the fee for service provisions of FIFRA §33 and qualifies as a fast track amendment. Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

¹ This information is available upon request.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 7, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MS. ANN TILLMAN
PYXIS REGULATORY CONSULTING, INC.
PROMIKA, LLC
4110 136TH STREET CT NW
GIG HARBOR, WA 98332-9122

PRODUCT NAME: PROMIKA ZOGUARD PLUS FOR DOGS
COMPANY NAME: PROMIKA, LLC
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 91300-5
EPA RECEIPT DATE: 08/04/17

SUBJECT: RECEIPT OF AMENDMENT

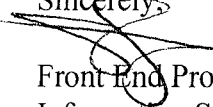
DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 3, at {Phone Number}.

Sincerely,


Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



Fee for Service {1007140A~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 3

Receipt No.

S- 1007140

EPA File Symbol/Reg. No.

91300-5

Pin-Punch Date:

8/4/2017

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *[Signature]*

Date: 8/6/2017

Remarks: Adding approved CRP to label



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 21, 2017

Kerrie Ihnen
Regulatory Manager
Promika, LLC
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Subject: CSF Notification per PRN 98-10 –Updating Basic CSF Product
Name: PROMIKA ZOGUARD PLUS FOR DOGS
EPA Registration Number: 91300-5
Application Date: 7/27/2017, 7/26/2017
Decision Number: 531944, 531890

Dear Ms. Ihnen:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 7/27/2017

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Angela Hollis at 703-347-0216 or by email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be "EF", written over a horizontal line.

for
Elizabeth Fertich, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 21, 2017

Kerrie Fersch Ihnen
Regulatory Manager
Promika, LLC
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Subject: Notification per PRN 98-10 – ABN
Product Name: PROMIKA ZOGUARD PLUS FOR DOGS
EPA Registration Number: 91300-5
Application Date: 7/14/2017
Decision Number: 531601

Dear Ms. Shorey:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name "*Heritage Plus for Dogs*" has been added to the product record.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "EF", is positioned above the typed name of the signatory.

for
Elizabeth Fertich, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
F: (253) 853-5516
ANN@PYXISRC.COM

July 27, 2017

ELECTRONIC SUBMISSION

Kable (Bo) Davis (PM 3)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Promika, LLC
Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5)
Notification to Add Alternate Supplier to Confidential Statement of Formula per PRN 98-10

Dear Mr. Davis,

On behalf of Promika, LLC, please find the enclosed notification which adds an alternate, registered source of one of the active ingredients to the CSF of Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5).

In support of this application, the following documents are enclosed:

1. Application for a Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4) for the revised Basic formulation dated July 27 2017.
3. Formulator's Exemption Statement (EPA Form 8570-27)
4. Letter of Authorization

The enclosed Basic CSF dated July 27, 2017 is meant to **REPLACE** the CSF submitted via notification dated July 26, 2017 and the current Basic CSF on file with EPA.

Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Ann M. Tillman".

Ann M. Tillman

Enclosures



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address
 Promika, LLC
 c/o Pyxis Regulatory Consulting, Inc.
 4110 136th St. CT NW
 Gig Harbor, WA 98332

EPA File Symbol/Registration Number
 91300-5

Product Name
 Promika ZoGuard Plus for Dogs

Date of Confidential Statement of Formula (EPA Form 8570-4)
 Jul. 27, 2017

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fipronil
S-methoprene

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) of (3).

(3) Indicated by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Fipronil	[REDACTED]	[REDACTED]
S-methoprene	[REDACTED]	[REDACTED]

Signature

Name and Title

Ann M. Tillman | Agent

Date

Jul. 27, 2017

	Environmental Protection Agency United States Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide – Section I

1. Company/Product Number Promika LLC/91300-5	2. EPA Product Manager Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Promika, LLC/Promika ZoGuard Plus for Dogs	PM# 3	
5. Name and Address of Applicant (include ZIP Code) Promika, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
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Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

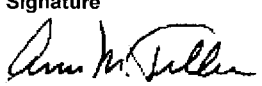
CSF Notification of addition of alternate suppliers—submission of revised Basic CSF. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you should have any questions concerning this submission, please contact me by e-mail at Ann@PyxisRC.com or by phone at (253) 853-7369.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) bulk HDPE or coated metal drums		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136 fl. oz.	No. per container 3, 6, 12	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.069, 0.135, 0.273, 0.408 fl oz; bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other on box and insert <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date Jul. 27, 2017	



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
F: (253) 853-5516
ANN@PYXISRC.COM

July 26, 2017

ELECTRONIC SUBMISSION

Kable (Bo) Davis (PM 3)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Promika, LLC
Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5)
Notification to Add Alternate Suppliers to Confidential Statement of Formula per PRN 98-10

Dear Mr. Davis,

On behalf of Promika, LLC, please find the enclosed notification which adds an alternate, registered source of one of the active ingredients to the CSF for Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5). In addition, one of the current sources of the other active ingredient in the formulation was transferred and this revised CSF updates the information with the current registrant name and EPA Reg. No.

In support of this application, the following documents are enclosed:

1. Application for a Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4) for the revised Basic formulation dated July 26, 2017.
3. Formulator's Exemption Statement (EPA Form 8570-27)
4. Letter of Authorization

The enclosed Basic CSF dated July 26, 2017 is meant to **REPLACE** the currently approved Basic CSF on file with the Agency.

Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Ann M. Tillman".

Ann M. Tillman

Enclosures



Environmental Protection Agency

United States
Washington, DC 20460

- ☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number Promika LLC/91300-5	2. EPA Product Manager Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Promika, LLC/Promika ZoGuard Plus for Dogs	PM# 3	
5. Name and Address of Applicant (include ZIP Code) Promika, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- ☐ Amendment – Explain below. ☐ Final printed labels in response to Agency letter dated _____
- ☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application.
- ☒ Notification – Explain below. ☐ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

CSF Notification of addition of alternate suppliers—submission of revised Basic CSF. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you should have any questions concerning this submission, please contact me by e-mail at Ann@PyxisRC.com or by phone at (253) 853-7369.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) bulk HDPE or coated metal drums
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136 fl. oz.	No. per container 3, 6, 12

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 0.069, 0.135, 0.273, 0.408 fl oz; bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other on box and insert		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
------------------------	----------------	---

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature 	3. Title Agent
4. Typed Name Ann M. Tillman	5. Date Jul. 26, 2017



ELECTRONIC SUBMISSION

July 14, 2017

Bo Davis (PM 3/4)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7540P)
U.S. Environmental Protection Agency
Room 5-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

RE: Promika, LLC – Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5)
Notification of an Alternate Brand Name per PRN 98-10

Dear Mr. Davis,

Promika, LLC would like to submit the enclosed notification of an alternate brand name per PRN 98-10 for Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5).

The alternate brand name being added is “**Heritage Plus for Dogs**”.


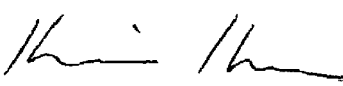
In support of this notification, please find the enclosed documents:

1. Application for Pesticide Registration (EPA Form 8570-1)
2. One (1) copy of the proposed labeling with changes tracked
3. One (1) copy of the proposed labeling with changes incorporated

If you have any questions or need any additional information, please contact me at 984-664-9804 or Kerrie.Ihnen@CSELifeScience.com.

Sincerely,

Kerrie Fersch Ihnen

 Environmental Protection Agency United States Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number 91300-5		2. EPA Product Manager B. Davis	
4. Company/Product (Name) Promika, LLC / Promika ZoGuard Plus for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (include ZIP Code) Promika, LLC 501 Cascade Pointe Lane Suite 102 Cary, NC 27513		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Notification – Explain below. <input type="checkbox"/> Other – Explain below.			
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Notification of an alternate brand name per PRN 98-10. The alternate brand name is "Heritage Plus for Dogs". This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Bulk-HDPE or coated metal drums
* Certification must be submitted If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136 fl oz		No. per container 1,3,6	If "Yes" Package wgt. ---
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container CRP 0.069, 0.135, 0.273, 0.408 fl oz/ 0.138, 0.27, 0.546, 0.816 fl oz; non-CRP 0.68 fl oz; bulk 55, 275 gal	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Kerrie Ihnen		Title Regulatory Manager	Telephone No. (Include Area Code) (984) 664-9804
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Manager	
4. Typed Name Kerrie Ihnen		5. Date July 14, 2017	

PROCESSING REQUEST

Reg # 91300-5 Decision # 527494

Description: Revised Basic

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 3/8/17

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Julie Breeden-Alemi

Division: RD/IVB 1

Phone: 703-347-0511

Date: 5/16/17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 16, 2017

Ann M. Tillman, Ph.D.
Promika, LLC
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. Ct. NW
Gig harbor, WA 98332

Subject: CSF Amendment – revised Basic CSF
Product Name: Promika ZoGuard Plus for Dogs
EPA Registration Number: 91300-5
Application Date: 9-March-2017
Decision Number: 527494

Dear Dr. Tillman:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 03/08/2017

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within a large, loopy oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Breeden-Alemi, Julie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Monday, May 15, 2017 12:45 PM
To: Breeden-Alemi, Julie
Subject: RE: Reg. No. 91300-5 and -6 addendum to previous email
Attachments: 91300-6 20170515 8570-1 Application Form.pdf, 91300-5 20170515 8570-1 Application Form.pdf

Julie,

I corrected the forms.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: May 11, 2017 5:11 PM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: FW: Reg. No. 91300-5 and -6 addendum to previous email

Also just noticed: In section 3 box 2 on each application form, the reference to Bulk: HDPE or coated metal drums should be removed.

Thanks again, Ann, have a nice evening,
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1

From: Breeden-Alemi, Julie
Sent: Thursday, May 11, 2017 4:59 PM
To: 'Ann Tillman' <Ann@PyxisRC.com>
Subject: Reg. No. 91300-5 and -6

Hi Ann,

I hope you had a nice day.

I am finishing up the CSF amendments for Reg. No. 91300-5 and -6 wanted to touch base with you about the information in section III of the application form (8570-1 form) dated March 9, 2017 and how it corresponds to the Net Contents on the Master Label and CRP certifications. The way I reconcile the information from the CRP certifications and the Net Contents on the respective Master Labels, I deduce the following:

For Dogs (91300-5):

No. per container... should this be 3, 6, 12 (with removal of the 1, addition of the 12)

Size (s) Retail Container...should this be (0.023, 0.045, 0.091, 0.136) x3, 6, 12 (with removal of the Bulk)

For Cats (91300-6):

No. per container... should this be 1, 3, 6, 12 (with addition of the 12)?

Size (s) Retail Container...should this be 0.017, 0.051, 0.102, 0.204 (with removal of the Bulk)?

Please help clarify the information included on the application form as it corresponds to the CRP certifications and Master Label for the products. Once we make any necessary revisions to the application forms, I will be able to move the actions forward.

Thanks for your help,
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511
Office: S-7216, Mail Code: 7505P



UNITED STATE ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION(7505P)

DOCUMENT CONTAINS CONFIDENTIAL INFORMATION

DATE OUT: May 9, 2017

DP BARCODE No.: 438961

REG. No.: 91300-5

Decision No: 527494

Action Code: 345

Company Name: Promika, LLC

Product: "Promika ZoGuard Plus for Dogs"

PC Code: 105402; 129121

FROM: William Herald, Microbiologist (MS) /Chemist, REHS/ Registered Sanitarian
Chemistry, Inerts and Toxicology Assessment Branch (CITAB) RD (7505P)

TO: Julie Breeden / Kable Davis, PM 3
Invertebrate Vertebrate Branch 1/ RD (7505P)

*Approved
SJB
5/10/17*

INTRODUCTION:

With a letter dated March 9, 2017 Registrant, Promika, LLC has submitted a revised Basic CSF formulation (dated 3/8/2017) to support the registration of the end use product, "Promika ZoGuard Plus for Dogs". In the proposed Basic formulation Registrant has modified two of the inert ingredients. CITAB has been asked to evaluate the said revised Basic CSF formulation and determine its acceptability.

SUMMARY OF FINDINGS:

1. The proposed end use product contains [REDACTED] and [REDACTED] as the active ingredients with the product label claims as 9.80% and 8.80% respectively.
2. The said proposed Basic formulation is filled out correctly and completely. The nominal concentration of the active ingredients concur with the product label in compliance with PR Notice 91-2.
3. The upper and lower limits of the active and inert ingredients are in compliance with the statutory parameters recited in Title 40 CFR 158.350 (b) (2).
4. The inert components have been cleared by the Agency for non-food use by the Agency (R. Rosario, 3/15/17).

CONCLUSIONS:

1. The CITAB has reviewed the revised Basic CSF formulation March 8, 2017 and has determined it to be acceptable.
2. The proposed Basic CSF dated March 8, 2017 supersedes the current Basic CSF.

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

May 4, 2017

MEMORANDUM:

Subject: Name of Pesticide Product: PROMIKA ZOGUARD PLUS FOR DOGS
EPA Reg. No. /File Symbol: 91300-5
DP Barcode: DP 438960
Decision No.: 527494
Action Code: 345
Submission: #1000402
E-Sub. 17940
PC Codes: 105402 (S-Methoprene: 8.8%)
129121 (Fipronil: 9.8%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Byron T. Backus
May 4, 2017

Through: P.V. Shah, Ph.D., Branch Chief
CITAB
Registration Division (7505P)

P.V. Shah
5/4/2017

To: Julie Breeden-Alemi / Kable Davis, RM 03
IVB1
Registration Division (7505P)

Registrant: PROMIKA, LLC

FORMULATION FROM PROPOSED LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.80%
105402 (S)-Methoprene	8.80%
<u>Other Ingredients:</u>	<u>81.40%</u>
TOTAL	100.00%


ACTION REQUESTED: "...Promika LLC wishes to replace the current Basic CSF dated 2/22/16 with the proposed CSF dated 3/8/17 for the product Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5)... Included in this BEAN are the following documents: cover letter, proposed Basic CSF, currently accepted Basic CSF, SDS sheets, and the product label...

Please review the submitted materials to determine if the revised Basic CSF is acceptable and if any revisions to the precautionary language are necessary..."

BACKGROUND: This product is a spot-on for use on dogs. The material available for review includes a cover letter (dated March 9, 2017), currently accepted and proposed CSFs, and one or more Safety Data Sheets.

COMMENTS AND RECOMMENDATIONS:

1. After a comparison of the currently accepted CSF (dated 2/22/2016) with the proposed basic CSF (dated March 8, 2017) for 91300-5, and after a review of the Safety Data Sheet material, CITAB concludes that the two formulations are toxicologically substantially similar.
2. The proposed basic CSF (dated March 8, 2017) for 91300-5 is acceptable. No revisions to the current use, precautionary or first aid statements are necessary.

 Environmental Protection Agency United States Washington, DC 20460	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
---	--	-----------------------

Application for Pesticide – Section I

1. Company/Product Number Promika LLC/91300-5	2. EPA Product Manager Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Promika, LLC/Promika ZoGuard Plus for Dogs	PM# 3	
5. Name and Address of Applicant (include ZIP Code) Promika, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input checked="" type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
--	---


Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Non-PIRA, fast track CSF amendment to replace the Basic Confidential Statement of Formula.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136 fl. oz.	No. per container 3,6,12	If "Yes" Package wgt. _____	No. per container _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 3x, 6x, 12x (0.023, 0.045, 0.091, 0.136) fl oz		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other on box and insert <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date May. 15, 2017	

 Environmental Protection Agency United States Washington, DC 20460	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number Promika LLC/91300-5	2. EPA Product Manager Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Promika, LLC/Promika ZoGuard Plus for Dogs	PM# 3	
5. Name and Address of Applicant (include ZIP Code) Promika, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
--	---


Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Non-PIRA, fast track CSF amendment to replace the Basic Confidential Statement of Formula.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) <u>bulk: HDPE or coated metal drums</u>		
* Certification must be submitted If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136 fl. oz.		No. per container <u>3, 6, 12</u>	If "Yes" Package wgt. _____	No. per container _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.069, 0.135, 0.273, 0.408 fl oz; <u>bulk</u>		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other <u>on box and insert</u>					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann M. Tillman	5. Date Mar. 09, 2017	



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
F: (253) 853-5516
ANN@PYXISRC.COM

March 9, 2017

ELECTRONIC SUBMISSION

Kable (Bo) Davis (PM 3)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Promika, LLC
Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5)
Submission of Non-PRIA Fast Track CSF Amendment

Dear Mr. Davis,

On behalf of Promika, LLC, we are submitting an amendment to revise the CSF for Promika ZoGuard Plus for Dogs, an end use product containing the active ingredients fipronil and (S)-methoprene. The following changes were made to the formulation:

- Addition of [REDACTED] each of [REDACTED] of the product

In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4) for the current Basic formulation dated February 22, 2016.
3. Confidential Statement of Formula (EPA Form 8570-4) for the revised Basic formulation dated March 8, 2017. This revised CSF is meant to **replace** the current approved version dated February 22, 2016.
4. One (1) copy each of the SDSes for the [REDACTED]
5. Formulator's Exemption (EPA Form 8570-27)
6. Letter of Authorization

The addition of these [REDACTED] in Promika ZoGuard Plus for Dogs

- does not change the nominal concentration of the active ingredient;
- does not invalidate any product-specific data submitted in support of the initial registration which would cause additional data to be required;
- does not change the product's acute toxicity category or physical/chemical properties requiring label modifications; and
- does not affect the product's efficacy or safety.

Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,

Ann M. Tillman

Enclosures

Inert ingredient information may be entitled to confidential treatment



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Promika, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. CT NW Gig Harbor, WA 98332	EPA File Symbol/Registration Number 91300-5
	Product Name Promika ZoGuard Plus for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) Mar. 08, 2017

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Fipronil
S-methoprene

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) of (3).

- (3) Indicated by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with EPA is complete, current, and accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Fipronil	[REDACTED]	[REDACTED]
S-methoprene	[REDACTED]	[REDACTED]
Signature 	Name and Title Ann M. Tillman Agent	Date Mar. 09, 2017



September 11, 2015

To Whom It May Concern: RE: Letter of Authorization Dear Sir or Madam:

Please let this letter serve to confirm that Ann Tillman, Mike Kellogg, Leanne Pruette, Janelle Kay of Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Promika, LLC (EPA Company Number 91300), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Randall V Canady
Chief Executive Officer
Promika, LLC

cc: Pyxis Regulatory Consultants, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 10, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

ANN M. TILLMAN
PYXIS REGULATORY CONSULTING, INC.
AGENT FOR PROMIKA, LLC
4110 136TH STREET CT NW
GIG HARBOR, WA 98332-9122

PRODUCT NAME: PROMIKA ZOGUARD PLUS FOR DOGS
COMPANY NAME: PROMIKA, LLC
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 91300-5
EPA RECEIPT DATE: 03/09/17

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 3, at (703) 306-0415.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{1000402q~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr.

33

Receipt No.

S-

1000402

EPA File Symbol/Reg. No.

91300-5

Pin-Punch Date:

3/9/2017



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

PR 03/15/17

Parent/Child Decisions:



Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: Tiffany

Date: 3/10/17

Remarks: 362 - CSF amendment

FAST-TRACK AMENDMENTS - Completeness Screening Checklist

Expert's In-Processing Signature: Hawthorne SeamerDate: 3/13/17PM #: 3

EPA Reg. Number: <u>91300 - 5</u>		EPA Receipt Date: <u>3/9/2017</u>		
	Checklist Item	Yes	No	N/A
1	Application Form (EPA Form 8570-1) - signed?	X		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?		X	
3	Certification with Respect to Citation of Data (EPA Form 8570-34) - signed?		X	
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?		X	
5	Data Matrix (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?		X	
	a) Selective Method?			
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label included? (5 copies)		X	
	a) Electronic Label submitted?	X		
Comments: CSF Amendment Inert review Inerts approved for intended use. P. Rosario 03/15/17				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 3, 2017

Arianna Shorey
Regulatory Consultant
Promika, LLC
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Subject: Notification per PRN 98-10 – ABN
Product Name: PROMIKA ZOGUARD PLUS FOR DOGS
EPA Registration Number: 91300-5
Application Date: 1/20/2017
Decision Number: 525456

Dear Ms. Shorey:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name "Fortress Defense for Dogs" has been added to the product record.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", is written over a horizontal line.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
F: (253) 853-5516
ARIANNA@PYXISRC.COM

January 20, 2017

ELECTRONIC SUBMISSION

Bo Davis (PM 3/4)
Document Processing Desk (**NOTIF**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

RE: Promika, LLC – Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5)
Notification of an Alternate Brand Name per PRN 98-10

Dear Mr. Davis,

On behalf of Promika, LLC please find the enclosed notification of an alternate brand name per PRN 98-10 for Promika ZoGuard Plus for Dogs (EPA Reg. No. 91300-5).

The alternate brand name being added is "**Fortress Defense for Dogs**".

In support of this notification please find the enclosed documents:

1. Application for Pesticide Registration (EPA Form 8570-1)
2. One (1) copy of the proposed labeling with changes tracked
3. One (1) copy of the proposed labeling with changes incorporated
4. Letter of Authorization

Please feel free to contact me at 253-853-7369 or Arianna@pyxisrc.com if you should have any questions or need any additional information.

Sincerely,



A handwritten signature in black ink that reads "Arianna Shorey". The signature is written in a cursive, flowing style.

Arianna Shorey

Enclosures

cc: Promika, LLC

DOCUMENTUM

 Environmental Protection Agency United States Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number 91300-5		2. EPA Product Manager B. Davis	
4. Company/Product (Name) Promika, LLC / Promika ZoGuard Plus for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (include ZIP Code) Promika, LLC c/o Pyxis Regulatory Consulting Inc. 4110 136 th St. Ct. NW Gig Harbor, WA 98332		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Notification – Explain below. <input type="checkbox"/> Other – Explain below.			
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Notification of an alternate brand name per PRN 98-10. The alternate brand name is "Fortress Defense for Dogs". This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Bulk-HDPE or coated metal drums
* Certification must be submitted If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136 fl oz		No. per container 1,3,6	If "Yes" Package wgt. _____ No. per container _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container CRP 0.069, 0.135, 0.273, 0.408 fl oz/0.138, 0.27, 0.546, 0.816 fl oz; non-CRP 0.68 fl oz; bulk 55, 275 gal	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Arianna Shorey		Title Regulatory Consultant	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) <div style="font-size: 2em; opacity: 0.5;">DOCUMENTUM</div>
2. Signature 		3. Title Regulatory Consultant	
4. Typed Name Arianna Shorey		5. Date Jan. 20, 2017	

PROCESSING REQUEST

Reg # 91300-5

Decision # 512125

Description: New product Registrations

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: BASIC CSF 2/22/16

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Julie Breeden-Alemi

Division: RD/IVB 1

Phone: 703-347-0511

Date:

10/4/16



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

91300-5

Date of Issuance:

10/4/16

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 10/04/2018

Name of Pesticide Product:

Promika ZoGuard Plus for Dogs

Name and Address of Registrant (include ZIP Code):

Ann. M. Tillman, Ph.D.
Promika, LLC
c/o Pyxis Regulatory Consulting, Inc.
4110 136th Street. CT NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Bo Davis, Product Manager 03
Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

Date:

10/4/16

2. This registration is time-limited and expires 10/04/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred (mm/dd/yyyy)
 - State in which the incident occurred (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Fipronil GDCI-129121-1305
GDCI-129121-152

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation

Division: <http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

6. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
7. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 91300-5."
8. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 02/22/2016

If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Enclosure

[text in [] denotes optional language]

{text in {} denotes location of text on packaging, notes to reviewer, text that will not be on final label}

(text in () appears on label)

{Front Panel of Carton}

Promika ZoGuard Plus for Dogs

{The word "Dogs" in the product name will be 75% of the height of the largest letter in the primary brand name.}

{Large clear picture of dog in appropriate breed/weight class on front panel to be included}



{a 1.5cm x 1.5cm cat prohibition icon in a box located at the lower right hand corner of the front panel in yellow with black images}

{The following statements will appear on the front panel.}

For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR}
For use ONLY on dogs and puppies 5[-] [to] 22 lbs and 8 weeks or older {OR}
For use ONLY on dogs & puppies 5[-] [to] 22 lbs and 8 weeks or older {OR}
ONLY For Dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR}
ONLY For Dogs & Puppies 8 weeks or older and 5[-] [to] 22 lbs {OR}
ONLY For Dogs & Puppies 8 weeks or older & 5[-] [to] 22 lbs

{Optional Marketing Claim}

[[3][6][12] Month Supply]

{When used, all three optional statements below will appear together on the same panel.}

[Contains Fipronil and (S)-Methoprene, the active ingredients used in FRONTLINE® Plus for Dogs]

[Frontline is a registered trademark of Merial]

[(Brand Name) is not manufactured or distributed by Merial, seller of Frontline® Plus for Dogs]

{See optional graphics on page 8 of this label that may or may not appear on front panel of carton}

ACTIVE INGREDIENTS:

Fipronil..... 9.80%

(S)-Methoprene..... 8.80%

OTHER INGREDIENTS: 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements and First Aid

See Side Panel for Storage and Disposal

See inside panels and insert for additional Directions for Use

Net Contents: X fl. oz. [(mL)]

[3][Three][6][Six][12][Twelve]

[[3][6][12] Applications]

[0.023 fl oz (0.67 mL) applicators] [0.045 fl oz (1.34 mL) applicators]

[0.091 fl oz (2.68 mL) applicators]] [0.136 fl oz (4.02 mL) applicators]

{BACK PANEL OF CARTON}

ACCEPTED

10/04/2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 91300-5

[In Case of Emergency, call: XXX-XXX-XXXX]

[Non-Emergency, call XXX-XXX-XXXX]

[Formulated in USA]

[Manufactured For][Distributed By]:

Promika, LLC.

501 Cascade Pointe Lane, Suite 102

Cary, NC 27513

EPA Reg. No. 91300-XX

EPA Est. No. XXXX-XXX-XXX

READ ENTIRE LABEL BEFORE EACH USE.

{One of these statements will be used}

USE ONLY ON DOGS AND PUPPIES 5 LBS AND OVER & 8 WEEKS OF AGE OR OLDER {OR} USE ONLY ON DOGS AND PUPPIES 5 LBS AND OVER AND 8 WEEKS OF AGE OR OLDER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

FIRST AID	
If in eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
If swallowed	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If on skin	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, you may contact SafetyCall at 1-844-685-9173 seven days a week, 24-hours a day.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs.

{The following text in a box will be placed in the lower right hand corner of back panel immediately above the cat warning box.}

Side Effects (Dogs): Monitor your dog after application. Some dogs may experience temporary startle effects when any product is applied. Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. In some cases gastrointestinal signs such as vomiting and diarrhea may occur. If these or other side effects occur, consult your veterinarian or call SafetyCall at 1-844-685-

9173. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application.

How to open:

Refer to package insert for directions on how to open package.

How to apply:

Remove product applicator from the package. Separate one applicator from the others. Hold the applicator with notched end pointing up and away from the face and body.

[Snap the outline of the tip back to allow access to the [dotted tip of the] applicator]]. {OR}

[Snap the applicator tip [backwards] [across the marked line] [to allow access to the] [dotted tip] [notches]]. {OR}

[Holding the applicator away from your and your dog's eyes, snap the applicator tip [at notched line] to open.]

Invert applicators over dog and use open end to part dog's hair. Squeeze applicator firmly to apply all of the solution to a single spot on the dog's skin, as directed below. Do not apply more often than once every 4 weeks.

{For cartons containing 0.67 mL (0.023 fl oz) applicators}

Only For Dogs Weighing 5 [-] [to] 22 lbs. & 8 weeks and older. Do not apply to dogs or puppies weighing less than 5 lbs.

Apply one applicator (0.67 mL)(0.023 fl oz)

[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 1.34 mL (0.045 fl oz) applicators}

Only For Dogs Weighing 23 [-] [to] 44 lbs. & 8 weeks and older.

Apply one applicators(1.34 mL)(0.045 fl oz)

[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 2.68 mL (0.091 fl oz) applicators}

Only For Dogs Weighing 45 [-] [to] 88 lbs. & 8 weeks and older.

Apply one applicator (2.68 mL)(0.091 fl oz)

[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 4.02 mL (0.136 fl oz) applicators}

Only For Dogs Weighing 89 [-] [to] 132 lbs. & 8 weeks and older. Do not use more than one applicator per treatment for one dog regardless of the dog's weight.

Apply one applicator (4.02 mL)(0.136 fl oz)

[as a spot [on] [to] the dog's back between the shoulder blades.]

FREQUENCY OF APPLICATION

Use [Brand Name] [this product] monthly for control of fleas, ticks, [and] chewing lice, [and] mosquitos. [Studies show that] [Brand Name] [this product] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Avoid contact with treated area until dry. Do not reapply for [30 days] [4 weeks].

{a 1.5 cm x 1.5 cm cat prohibition icon and warning text in a box, black on yellow background, will be placed on the lower right hand corner of back panel.}



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

{INSIDE PANELS OF CARTON}

Promika ZoGuard Plus for Dogs

{The following statements will appear on the inside panel of the carton.}

For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR}
For use ONLY on dogs and puppies 5[-] [to] 22 lbs and over 8 weeks of age {OR}
For use ONLY on dogs & puppies 5[-] [to] 22 lbs and over 8 weeks of age {OR}
ONLY For Dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] and 8 weeks or older {OR}
ONLY For Dogs & Puppies 8 weeks or older and 5[-] [to] 22 lbs {OR}
ONLY For Dogs & Puppies 8 weeks or older & 5[-] [to] 22 lbs

[[Brand Name] [This product] contains Fipronil and (S)-Methoprene [insect growth regulator] [IGR] to effectively kill fleas and ticks [including those that may transmit Lyme disease]. [The active ingredients in [Brand Name][This product] features a formula developed for fast acting [and long lasting for up to [4 weeks][30 days]] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

[Application Instructions] {OR} [Directions for Use]

How to Open

Refer to package insert for directions on how to open package.

How to Apply

Remove product applicator from the package.

Separate one applicator from the others. Hold the applicator with notched end pointing up and away from the face and body.

[Snap the outline of the tip back to allow access to the [dotted tip of the] applicator]]. {OR}

[Snap the applicator tip [backwards] [across the marked line] [to allow access to the] [dotted tip] [notches]]. {OR}

[Holding the applicator away from your and your dog's eyes, snap the applicator tip [at notched line] to open.]

Invert applicator over dog and use open end to part dog's hair.

[Squeeze applicator firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.]

Allow the area to dry. Avoid contact with treated area until dry. Only one applicator per treatment is needed.

RESTRICTIONS

Do not allow your dog to ingest this product.

Do not use on puppies under 8 weeks of age and less than [5][23][45][89] lbs.

Use entire contents of applicator on each dog.

Do not split one applicator between dogs.

Do not use multiple applicators on one dog.

Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.

Be sure your dog is dry before application and keep your dog dry for 24 hours after application.

Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Do not apply more frequently than once every 4 weeks.

[Optional pictogram]



[Look at the Label (Look at the Label icon) [Easy]

6 Step [Easy] [Spot On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog

- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate dogs after [treatment] [application] from other animals to avoid chance of ingestion
- [6] Do NOT split applicators between dogs [and use the ENTIRE applicator contents]

Promika, LLC.
501 Cascade Pointe Lane, Suite 102
Cary, NC 27513

[WARRANTY] [LIMITATION OF WARRANTY AND LIABILITY]

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of [Company]. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, [Company] makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither [Company], the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.]

{SIDE PANEL 1}

[[Brand name]][This product]. Three month supply. ONLY for Dogs & Puppies 8 weeks or older and 5 lb. or over

{SIDE PANEL 2}

[[Brand name]][This product]. ONLY for Dogs & Puppies 8 weeks or older and 5 lb. or over

{SIDE PANEL 3}

[[Brand name]][This product]. ONLY for Dogs & Puppies 8 weeks or older and 5 lb. or over

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Do not remove applicator from the pack until ready to use. Store in a cool (below 77°F [7][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. **If empty:** Offer for recycling if available **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

{Optional recycling graphic}



{SIDE PANEL 4}

[[Brand name]][This product]. ONLY for Dogs & Puppies 8 weeks or older and 5 lbs and over

[BAR CODE AREA]

[Lot code; only number will appear]

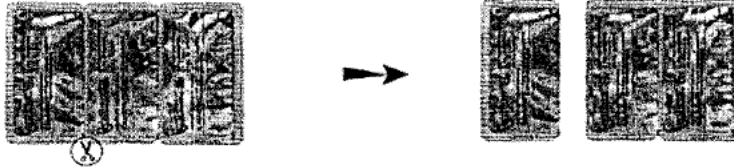
{Begin Package Insert}

Promika ZoGuard Plus for Dogs

How to Open:

REMOVE AND OPEN PACKAGE

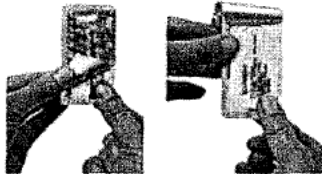
- 1.** Cut along scissor cut line to separate unit



- 2.** Turn unit over and cut corner at bulb end



- 3.** From cut corner, peel backing completely off from bottom to top



- 4.** Remove the applicator





OPEN APPLICATOR

Hold upright with foil side away from you and snap applicator tip back to open.


{End Package Insert}

{Optional graphics below may or may not appear anywhere on finished label}

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	

{May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from an applicator on front, side, back, inside carton panels.}

{START – APPLICATOR LABEL}

<p>{Brand Name}</p> <p>For Dogs [X-Y] lbs and ≥ 8 wks</p> <p>fipronil 9.8%, (S)-methoprene 8.8%</p> <p>0.023 fl oz {or} 0.045 fl oz {or} 0.091 fl oz {or} 0.136 fl oz</p> <p>Lot/Batch No. {only number will appear}</p>		<p>KEEP OUT OF REACH OF CHILDREN</p> <p>CAUTION. Read accompanying label before use.</p> <p>[Use scissors to open.]</p> <p>EPA REG. No. 91300-xx</p>
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{END – APPLICATOR LABEL}

{START – OUTER BLISTER LABEL}

<p>{Brand Name}</p> <p>For Dogs [X-Y] lbs ≥ 8 wks</p> <p>fipronil 9.8%, (S)-methoprene 8.8%</p> <p>0.023 fl oz {or} 0.045 fl oz {or} 0.091 fl oz {or} 0.136 fl oz</p> <p>Lot/Batch No. {only number will appear}</p>	<p>KEEP OUT OF REACH OF CHILDREN</p> <p>CAUTION. For External Use Only. Read accompanying label before use.</p> <p>EPA REG. No. 91300-xx {label code}</p>
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{IMAGE FOR OUTER BLISTER LABEL}



{END – OUTER BLISTER LABEL}

{Optional Marketing Claims}

Mosquitoes

Kills mosquitoes [within 24 hours for up to 7 days and within 48 hours for up to 28 days, with monthly application]

Chewing Lice

Kills chewing lice

Rapid elimination of chewing lice infestations

A once monthly application required to control chewing lice

Adult Fleas

Kills [adult] Fleas

Kills newly emerged adult Fleas before they lay eggs

Kills Adult Fleas, which may be a source of flea allergy dermatitis

Kills Fleas Up to [4 weeks] [1 month] [30 days]!

If dog is a high risk for flea reinfestation, a once month application may be needed

Multiple Infestations

Kills chewing lice [and controls mites that may cause sarcoptic mange]

Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 5 lbs and over and 8 weeks old [&] [and] older

Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]

Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]

Kills Fleas, Ticks [&] [and] [Mosquitoes]

Breaks the Flea Life Cycle [when used monthly]

Monthly flea, tick, [mosquito], chewing lice and flea egg protection

Monthly flea, tick, [mosquito] and chewing lice protection

Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice

[Seven] [7] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae

[Six] [6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae

[Five] [5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs & flea larvae

[Six] [6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs & flea larvae

[Five] [5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs & flea larvae

[Four] [4] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs

[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!

[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]

[Four [4] Week] [1 month] Flea, Tick, [Mosquito] and Chewing Lice Control

Use [Brand Name][This product] monthly to break the flea life cycle

Use [Brand Name][This product] monthly to control ticks and chewing lice

Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection

Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]

Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!

Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!

Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]

Ticks

Kills Ticks including those that may transmit Lyme disease

Kills Ticks for Up to [4 weeks] [1 month] [30 days]!

Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days]] [per application]

Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]

Kills [brown dog ticks [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks][,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]

Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!

Flea Eggs and Larvae

Controls flea reinfestation

Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae.

Effectively controls all stages of the flea [including adult fleas, flea eggs, flea larvae] and prevents the development of flea pupae

Effective against all stages of the flea [including adult fleas, flea eggs, flea larvae] and prevents the development of flea pupae

If dog is a high risk for flea reinfestation, a once month application may be needed

Prevents from developing, flea eggs [larvae] [pupae]

With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle

With (S)-methoprene to Break Flea Life Cycle

With Insect Growth Regulator [IGR] to Break Flea Life Cycle

Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle

Kills Flea Eggs & Flea Larvae!

Prevents Flea Eggs From Developing Into Biting Adults

Prevents all stages of the flea life cycle from developing

Controls reinfestation of fleas

Effective against all stages of the flea life cycle

Effectively controls all stages of the flea life cycle

All Others

For Dogs and Puppies 5 lbs and over and 8 weeks of age or older

Can be used on puppies 5 lbs and over and 8 weeks of age and older

For Dogs & Puppies 5 lbs and over and 8 weeks of age or older

For Dogs [5-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.] and 8 weeks of age or older

Convenient spot treatment

Fast Acting

Easy to Use [Application]

Best if used year round!

For year-round protection, apply [Brand Name] monthly

(ICON Showing [4 week] [1 month] [30 day] Protection)

Apply monthly

Prevents reinfestation of listed pests for [4 weeks] [1 month]

Apply once every [4 weeks] [month] [30 days]!

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[Three Applications][Six Applications][12 Applications]

[3 Month Supply][6 Month Supply][12 Month Supply]

Controls mites that may cause sarcoptic mange

Waterproof

Effective after bathing and exposure to water and sunlight

Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]

Fipronil (9.8%) + (S)-methoprene (8.8%)

Controls and prevents infestation of listed pests for [4 weeks][1 month]

Controls existing infestation and prevents establishment of additional infestation of listed pests

Lift [here] for more information

Open [here] for more information

Image of an arrow to show Open here for more information

{When used, all three optional statements will appear together.}

Contains Fipronil and (S)-methoprene, the active ingredients used in FRONTLINE® Plus for Dogs

Frontline is a registered trademarks of Merial

(Brand Name) is not manufactured or distributed by Merial



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Note to File

Date: October 4, 2016

Registration Number: 91300-5 (L)

Decision Number: 512125

PM/RM Name: Bo Davis/Julie Breeden-Alemi

Background: New product registration action submitted as an R315. Efficacy data did not match cited product. Efficacy review sent to Registrant.

Decision: Registrant opted to change to cite-all regarding Companion Animal Safety and Efficacy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Julie Breeden-Alemi, DVM

From: Eric Bohnenblust, Ph.D., Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Senior Entomologist

Date: September 15, 2016

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 435145

Decision no.: 512125

Submission no: 981528

Action code: R315

Product Name: Promika Zoguard Plus for Dogs

EPA Reg. No or File Symbol: 91300-L

Formulation Type: Spot-On

Ingredients statement from the label with PC codes included:

S-methoprene 8.8% PC: 105402

Fipronil 9.8% PC: 129121

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate):

Dogs 4 – 22 lb: 0.023 fl. oz. (0.67 mL) product per dog (6.9 – 37.9 mg fipronil/mg body weight, 6.2 – 34.0 mg methoprene/mg body weight)

Dogs 23 – 44 lb: 0.045 fl. oz. (1.34 mL) product per dog (6.8 – 13.1 mg fipronil/mg body weight, 6.1 – 11.7 mg methoprene/mg body weight)

Dogs 45 – 88 lb: 0.091 fl. oz. (2.68 mL) product per dog (6.8 – 13.3 mg fipronil/mg body weight, 6.1 – 12 mg methoprene/mg body weight)

Dogs 89 – 132 lb: 0.136 fl. oz. (4.02 mL) product per dog (6.8 – 10.1 mg fipronil/mg body weight, 6.1 – 9.1 mg methoprene/mg body weight)

Use Patterns: Monthly topical treatment for use on dogs over 4 lbs and 8 weeks of age to kill fleas, ticks, mosquitoes, chewing lice, and sarcoptic mange mites.

I. Action Requested: The registrant submitted 17 MRIDs to support efficacy of a spot-on product containing fipronil and s-methoprene applied to dogs against fleas, ticks, mosquitoes, mites, and chewing lice.

II. Background: The registrant submitted 17 MRIDs to support efficacy of a dog spot-on product against fleas, ticks, mosquitoes, chewing lice, and sarcoptic mange mites. The registrant is claiming that the product is substantially similar to EPA Reg. No. 65331-5; however, the registrant cited different studies than those supporting

EPA Reg. No. 65331-5. All studies were previously reviewed for other products (numerous DPs) and the acceptability of the studies was variable and the details necessary to determine if the studies support efficacy claims was lacking. MRIDs 45620501 and 45620504 were previously reviewed under DP 432610 and summaries of the conclusions from that review as they pertain to the proposed product are presented below. Because the cited studies were different than the studies supporting the similar product, all studies were reviewed to determine their applicability to support efficacy claims against fleas, ticks, mites, and mosquitoes for the proposed product. The Agency is not requiring submission of data to support efficacy claims against cat or dog lice, therefore those studies are not reviewed below and are listed as supplemental/unacceptable.

III. MRID Summary:

A. Previously Reviewed Studies:

45620501. An Efficacy of Frontline Spray, Frontline Top Spot, and ML-2,095,988 509T, for the Treatment and Control of *Trichodectes canis* in the Dog. (DP 432610).

Conclusion: Extraneous submission. The Agency does not require the submission of data to support efficacy claims against lice on companion animals.

45620504. PR&D 0024101: Frontline Spray/Frontline Spot-On/ML-2, 095, 988 509T/Dogs/Solution/Topical. (DP 432610).

Conclusion: Unacceptable. This study does not support claims that the proposed product kills itch mites at the tested application rate (Fipronil Top Spot applied at the labeled rate - 0.67 ml product on dogs up to 22 lb; 1.34 ml product on dogs 23-44 lb; 2.68 ml on dogs 45-88 lb) because mite counts in the treated and untreated control groups were not significantly different.

B. Newly Reviewed Studies:

45612701. Study Summaries: Frontline Plus for Dogs.

(1) (non-GLP) This MRID is a summary of multiple studies: two studies are reviewed above under MRIDs 45620501 (Vol. 4 page 7) and 45620504 (PR&D 0024101), two studies (PR&D 052301 and PR&D 0012901) were submitted as MRIDs 45620505 and 45620506 and are reviewed below separately, and the other studies are reviewed below to determine if they support the proposed product.

(2) Methods for newly reviewed studies:

ASR 19083/CLI276 and PR&D 0010201-02: This study evaluated the effects of Frontline Spray treatment and a 2% permethrin spray product on dermatological criteria and flea infestations associated with flea allergy dermatitis on dogs. A total of 167 dogs 0.3 to 15 years of age weighing between 1.6 and 45 kg were enrolled at 22 veterinary clinics in Europe, Australia, and the United States. Dogs were assigned to a group treated with either a 2% permethrin spray (100 mg permethrin/kg body weight) or Frontline spray (15 mg fipronil/kg body weight). There was no mention of a control group until the results section and the study does not indicate if it was a positive (permethrin) or untreated control. Flea counts were made on days 0, 14/21, 28/35, and 56/70 post treatment using a scale of 0 = no fleas to 3 = heavy infestation. Dogs were also assessed for the presence or absence of flea eggs and feces, and for the presence of numerous types of lesions.

PR&D 0010201-02: This study evaluated the efficacy of Frontline Spot-on against fleas, flea eggs, and other dermatological symptoms of flea allergy dermatitis on thirty-seven dogs. Dogs were dosed with Frontline Top Spot per label instructions but specific dosing in mg/kg was not provided. There was no untreated control treatment. Dogs were examined for the presence or absence of fleas, flea eggs, and dermatological symptoms prior to treatment and on days 0, 14, 30, 60, and 90 days after treatment. The pre-treatment count was used as the untreated control treatment.

(3) Results and Conclusions for Each Study:

ASR 19083/CLI276 and PR&D 0010201-02: Flea count scores were reduced, but were not presented in a format that allows for the calculation of percent efficacy. This study does not support efficacy claims for the proposed product because there was no adequate untreated control treatment and the tested sprayable formulation cannot support claims for a spot-on formulation.

PR&D 0010201-02: The Frontline treatment reduced the number of fleas on animals by over 95% when compared to the pre-treatment count. However, flea numbers for the pre-treatment counts were not provided. The incidence of dermatological symptoms was reduced, but the Agency does not allow claims directly against diseases or conditions. This study does not support efficacy claims for the proposed product because there is no adequate untreated control group, and the dose is given as “per label instructions” (not the lowest labeled dose) and not provided on an individual basis. In addition, while the percent reduction in flea populations is high, the initial infestation counts were not provided so we cannot determine what “97% efficacy” means.

(4) **Conclusion: Unacceptable.** This study does not support the proposed product because the use pattern (spray formulation) tested in several studies is different from the use pattern (spot-on) for the proposed product. Also, methods and results are not presented in adequate detail to assess their applicability to support the proposed product.

45620502. A Study to Determine the Effects of Treatment with Frontline Top Spot on the Prevalence and Severity of Flea Allergy Dermatitis in Dogs.

(1) non-GLP; conducted under GCP. This study is the same as PR&D 0010201-02 presented in MRID 45612701 above, but is presented by itself in considerably greater detail. The additional detail was reviewed to determine if the inadequacies articulated were addressed and could result in a re-classification of the study.

(2) **Methods:** Dogs were treated with Frontline Top Spot (0.67 ml product on dogs up to 22 lb; 1.34 ml product on dogs 23-44 lb; 2.68 ml on dogs 45-88 lb) on days 0, 30, and 60. There was no concurrent untreated control group as the pre-treatment flea count was used as the untreated control treatment.

(3) **Results:** The mean number of fleas per dog pretreatment was 7.4 fleas. The number of fleas on treated dogs was reduced by over 95% for all observation days. The number of dogs showing evidence of flea eggs and feces was reduced over 90% by 14 days post treatment and this reduction continued throughout the 90 day observation point. Dermatological conditions were reduced by varying levels depending on the condition.

(4) **Conclusion: Unacceptable.** This study does not support efficacy claims for the proposed product because the pretreatment count is not an adequate control, the number of fleas counted during the pretreatment counts was too low to adequately evaluate control, and dosing was not conducted at the lowest labeled rate. Treated and untreated dogs should be challenged with fleas several times during the month long period to show that efficacy lasts for a full month.

45620503. Evaluation of the Efficacy of RM1601C/35, in the Treatment of Flea-Allergy Dermatitis in the Dog, Compared with a Reference Product.

(1) non-GLP; conducted under GCP. This study is the same as ASR 19083/CLI276 and PR&D 0010201-02 presented in MRID 45612701 above, but is presented by itself in considerably greater detail. The additional detail was reviewed to determine if new information addressed the inadequacies articulated above could result in a re-classification of the study.

(2) **Methods:** The permethrin treatment was used as a positive control treatment instead of a placebo. The study cites ethical concerns as a reason for not using a placebo.

(3) **Results:** Flea counts were reduced, but on day 28/35 post initial treatment 9 dogs treated with fipronil still showed light flea infestations.

(4) **Conclusion: Unacceptable.** This study does not support efficacy claims for the proposed product because there was not an adequate untreated control group, and flea counts were not assessed in a manner which would allow for the calculation of percent efficacy. Moreover, a sprayable formulation of fipronil was tested and the Agency does not bridge data collected using sprayable formulations to support products formulated as spot-ons.

45620505. Frontline Spray/Frontline Spot-on/ML-2, 095, 988 509T/Dogs/Solution/Topical.

(1) non-GLP; conducted under GCP. This study is the same as PR&D 0052301 presented in MRID 45612701 above, but is presented by itself in considerably greater detail.

(2) **Methods:** This study tested efficacy of an untreated control, a 0.25% fipronil sprayable formulation, a 10% w/v fipronil spot-on product, and a 10% w/v fipronil and 9% w/v methoprene spot on product against *Sarcoptes scabiei* var. *canis*. Twenty-four dogs were split into four groups of six dogs and each group was treated on day 0. Dogs were treated with the spot-on products according to the label rate (0.67 ml product on dogs up to 22 lb; 1.34 ml product on dogs 23-44 lb; 2.68 ml on dogs 45-88 lb). Dogs were naturally infested with *Sarcoptes scabiei* var. *canis* and infestation was confirmed by taking skin scrapings from sites with active infestations and counting the mites. Lesions were assessed and skin scrapings were collected on day -1/0, 7, 14, 21, 27/28, 35, 49, 54/55, 63, 70, 77, and 83/84. The number of live and dead mites in each sample was counted.

(3) **Results:** The number of *Sarcoptes scabiei* var. *canis* was not significantly reduced by any of the treatments when compared to the untreated control group. Lesion scores were also not significantly lower on dogs treated with either spot-on treatment than in the untreated control group.

(4) **Conclusion: Unacceptable.** This study does not support efficacy claims for the proposed product because the study does not show efficacy of the products against *Sarcoptes scabiei* var. *canis*.

45620506. Frontline Spray & Top Spot/Dogs/Solution/Topical Clinical/Dose Confirmation/Ectoparasites, Mites, *Sarcoptes scabiei* var *canis*.

(1) non-GLP; conducted under GCP. This study is the same as PR&D 0012901 presented in MRID 45612701 above, but is presented by itself in considerably greater detail.

(2) **Methods:** This study evaluated the efficacy of an untreated control group, Frontline Spray, and Frontline Top Spot against *Sarcoptes scabiei* var. *canis* on dogs. Dogs were dosed on day 0 and day 28 with the Top Spot product according to the label rate (0.67 ml product on dogs up to 22 lb; 1.34 ml product on dogs 23-44 lb; 2.68 ml on dogs 45-88 lb). There were six replicates of each treatment. On days -1, 7, 21, 35, 49, and 63, skin scrapings were collected and counted for mites. Dogs were also scored for skin lesions on days -1, 7, 14, 21, 28, 35, 42, 49, 56, and 63.

(3) **Results:** Frontline Top Spot significantly reduced the mean number of mites per dog when compared to the control treatment starting on day 21 post treatment. The mean number of mites on Top Spot treated dogs was zero on days 35, 49, and 63. The mean number of mites on control dogs ranged from 0.9 to 3.0.

(4) **Conclusion: Unacceptable.** This study does not support efficacy claims because it took 21 days to achieve statistically significant efficacy, 100% efficacy was not achieved by a single dose, and the number of mites on control animals was low. In addition dosing was not conducted at the lowest labeled rate for the proposed product.

45866902. Study to Evaluate the Efficacy of Frontline Plus for Control of Mosquitoes, *Aedes Aegypti*, on Dogs.

(1) non-GLP; conducted under GCP.

(2) **Methods:** Two groups of eight dogs were used to test the efficacy of an untreated control and Frontline Plus (10% w/v + 9% w/v S-methoprene) against *Aedes aegypti* mosquitoes. Dogs weighed between 3.4 and 6.5 kg (7.5 – 14.3 lb). The eight dogs in the treatment group were dosed with the labeled rate (0.67 mL Frontline plus) on day 0. On days 1, 2, 7, 14, 21, and 28 dogs were sedated and individually placed into mosquito-proof cages with

approximately 100 female *Aedes aegypti* mosquitoes. After a 30 minutes exposure, engorged and non-engorged mosquitoes were aspirated into separate cartons. Dead mosquitoes were counted and removed at 24 and 48 hours post exposure. Any live mosquitoes remaining at 48 h post exposure were frozen and counted.

(3) **Results:** At 24 hours post exposure, the number of live mosquitoes on treated dogs was reduced by over 99% through 7 days post treatment when compared to the control group. On days 14-28 post treatment the number of live mosquitoes on treated dogs was reduced 34% or less when compared to the control group. At 48 hours post exposure, the number of mosquitoes on treated dogs was reduced by over 90% when compared to the control group through 21 days post application. At 48 hours post exposure on day 28, the number of live mosquitoes on treated dogs was only reduced by 57% when compared to the control treatment.

(4) **Conclusion: Unacceptable.** This study does not support efficacy claims because efficacy only lasted for 21 days and, for claims to be applicable to spot-on products, data must show efficacy against the target pest for the entire month period. In addition, only one species of mosquito was tested and data showing efficacy against *Culex*, *Aedes*, and *Anopheles* mosquitoes are necessary to support any claims against mosquitoes. Moreover, dosing was not conducted at the lowest labeled rate (6.8 mg fipronil/kg body weight) for the proposed product.

43121114. A Dose Titration Study to Determine the Optimal Spray Concentration of RM 1601 for Long Term Control of the Cat Flea *Ctenocephalides felis* and the Brown Dog Tick *Rhipicephalis sanguineus* in the Dog.

(1) non-GLP; conducted under GCP.

(2) **Methods:** This study evaluated the efficacy of an untreated control, three doses (2.9 mg, 6.6, and 12.1 mg fipronil/kg body weight) of a sprayable fipronil product (formulated at 0.125%, 0.25%, and 0.5%), and a 0.25% chlorpyrifos spray against cat fleas and brown dog ticks on dogs. Each treatment was replicated on six dogs. Dogs were treated with the respective products on day 0. Dogs were infested with 50 brown dog ticks and 100 fleas on days -2, 21, 28/29, 35/36, 42/43, 49/50, 56/57, 63/64, 71 (fleas only). Visual observations were made by parting the hair on days 1 and 2 and thereafter at 24 hours post inoculation, and comb counts were conducted on day 3 and thereafter at 48 hours post inoculation. Percent control was calculated based on the number of live fleas on control animals.

(3) **Results:** The total number of fleas counted on control animals was between 264 and 531 on all observations days (average 44-88.5 fleas per dog). The 2.9 mg fipronil/kg body weight treatment reduced the total number of live fleas on dogs by over 90% through 59 days post treatment for both visual and comb counts. The 6.6 and 12.1 mg fipronil/kg body weight treatments reduced the total number of live fleas by over 90% through 73 days post application for visual and comb counts. The total number of ticks counted on control animals was between 144 and 250 for all observation periods (24-42 ticks per dog). The 2.9 mg fipronil/kg body weight treatment reduced the total number of brown dog ticks on dogs by over 90% when assessed through comb counts on days 3 through 24 post treatment. On day 31 post the reduction of live ticks on treated dogs was 81% and was less than 80% for the remainder of the experiment (day 45). Visual counts of ticks yielded less than 90% efficacy for all observations on animals treated with the 2.9 mg fipronil/kg body weight dose. The 6.6 mg fipronil/kg body weight treatment reduced the total number of live ticks by over 90% through 38 days post application for visual and comb counts. The 12.1 mg fipronil/kg body weight treatment reduced the total number of live ticks by over 90% through 52 days post application for visual and comb counts.

(4) **Conclusion: Unacceptable.** This study does not support efficacy claims for the proposed product because the study tested a sprayable formulation and the Agency does not bridge data conducted using a sprayable formulation to support a spot-on formulation. Also, the study only tested once species of ticks; for any tick claims, data must show efficacy against three species.

43121115. A Dose Confirmation Study to Verify the Optimal Spray Concentration of RM 1601 for Long Residual Control of the Cat Flea (*Ctenocephalides felis*) and the Brown Dog Tick (*Rhipicephalus sanguineus*) in the Dog.

(1) GLP.

(2) **Methods:** This study tested two sprayable formulations of fipronil (0.125% fipronil and 0.25% fipronil), an untreated control, and a 2% permethrin sprayable product for efficacy against cat fleas and brown dog ticks on dogs.

(3) **Conclusion: Unacceptable.** This study does not support efficacy claims for the proposed product because the study tested a sprayable formulation and the Agency does not bridge data conducted using a sprayable formulation to support a spot-on formulation.

43121116. A Comparative Evaluation of Two Treatment Regimes Using RM 1601 Spray for Control of the Cat Flea *Ctenocephalides felis* on the Dog.

(1) GLP.

(2) **Methods:** This study tested two application rates (3 mL and 6 mL product/kg body weight) of a 0.25% fipronil spray product and an untreated control against cat fleas on dogs.

(3) **Conclusion: Unacceptable.** This study does not support efficacy claims for the proposed product because the study tested a sprayable formulation and the Agency does not bridge data conducted using a sprayable formulation to support a spot-on formulation.

43121117. Laboratory Evaluation of RM 1601 Spray for Control *Dermacentor variabilis* and *Rhipicephalus sanguineus* on the Dog.

(1) GLP.

(2) **Methods:** This study tested two application rates (3 mL and 6 mL product/kg body weight) of a 0.25% fipronil spray product, and an untreated control against two tick species on dogs.

(3) **Conclusion: Unacceptable.** This study does not support efficacy claims for the proposed product because the study tested a sprayable formulation and the Agency does not bridge data conducted using a sprayable formulation to support a spot-on formulation. For any efficacy claims against ticks, data must be submitted showing efficacy against three tick species.

43121118. An Investigation Study to Evaluate the Effect of Bathing of Laboratory Dogs on the Efficacy of RM1601 Spray.

(1) GLP.

(2) **Methods:** This study tested efficacy of an application rate of 3 mL product/kg body weight of a 0.25% fipronil spray product before and after bathing, and an untreated control against cat fleas and brown dog ticks on dogs.

(3) **Conclusion: Unacceptable.** This study does not support efficacy claims for the proposed product because the study tested a sprayable formulation and the Agency does not bridge data conducted using a sprayable formulation to support a spot-on formulation. For any efficacy claims against ticks, data must be submitted showing efficacy against three tick species.

43121122. Efficacy of RM1601C at 3 ml/kg and 6 ml/kg Against *Ixodes scapularis/dammini* Nymphs, *Dermacentor variabilis* Nymphs, *Amblyomma americanum* Nymphs, and *Ctenocephalides felides* Adults Using Treated Dog Hair as the Testing Substrate.

(1) GLP.

(2) **Methods:** This study tested efficacy on dogs of application rates of 3 mL and 6 mL product/kg body weight of a 0.25% fipronil spray product and an untreated control against cat fleas and nymphs of American dog ticks, deer ticks, and lone star ticks.

(3) **Conclusion:** This study does not support efficacy claims for the proposed product because the study tested a sprayable formulation and the Agency does not bridge data conducted using a sprayable formulation to support a spot-on formulation. Also, tests using tick nymphs cannot by themselves support efficacy claims against ticks; adult ticks should be used in testing.

43577712. Positive Referenced and Untreated Controlled. Confirmatory Laboratory Trial of RM1601E SPOT-ON Formulation Applied to Dogs as 3 Weight Class Defined Volumes for Control of the Cat Flea *Ctenocephalides felis*, the Brown Dog Tick *Rhipicephalus sanguineus*, and the American Dog Tick *Dermacentor variabilis*.

(1) non-GLP; conducted under GCP.

(2) **Methods:** This study evaluated the efficacy of a 10% w/v fipronil spot-on product, an untreated control, and a positive control (Defend EXspot) applied to dogs against cat fleas, brown dog ticks, and American dog ticks. There were 6 dogs in the control treatment, 6 dogs per weight class (3 weight classes = 18 dogs total) in the fipronil treatment group and 18 dogs in the positive control group. Dogs were treated on day 0. The tested Fipronil product was assumed to be of a similar density to the proposed product, therefore the reviewer calculated the fipronil doses applied to dogs as follows: for small dogs, range = 6.9 - 12.3 mg fipronil/kg body weight, average = 8.4 mg fipronil/kg body weight; medium dogs, range = 9.7 - 11.8 mg fipronil/kg body weight, average = 10.45 mg fipronil/kg body weight; for large dogs, range = 9.4 - 13.2 mg fipronil/kg body weight, average = 11.0 mg fipronil/kg body weight. Dogs were anesthetized and infested with 50 ticks of each species on days -2, 13, 20, 27, 34, 41, and 48. Flea inoculations were conducted on days -2, 14, 21, 28, 36, 42, 49, 56, 63, 70, and 77. Fleas and ticks were counted on days 1, 2, 15, 22, 29, 37, 43, and 50. Fleas only were counted on days 57, 64, 71, and 78. Fleas and ticks were removed from the animals during comb counts for all observations except on day 1. Counts on day one were conducted using visual observations. Flea and ticks counts are presented as geometric and arithmetic means.

(3) **Results:** The results using arithmetic means are presented in this section. The average number of fleas counted on control animals was between 74 and 94 for all comb counts. The percent control of adult fleas provided by the fipronil treatment was over 98% through 50 days post treatment. After 50 days, control of adult fleas was reduced by less than 90% for days 64 through 78, while control on day 57 was 89.3%. The number of American dog ticks in the control and fipronil treated groups can be found in table 1 below; 90% efficacy or greater was achieved through day 29 and on day 37 89.3% control was observed. On days 15 and 22, attachment of ticks on control dogs was low, but attachment on control animals was acceptable on days 29 and 36. For brown dog tick (Table 2 below), attachment on control animals was low after day 2, although greater than 90% efficacy on treated animals was observed through day 29.

Table 1. Individual dog and group mean tick (*Dermacentor variabilis*) counts after treatment with RM1601E

GROUP	DOG	Treatment Day								
		5	1	2	15	22	29	36	43	50
A	410	26	65	74	15	9	29	14	12	18
	414	35	40	49	2	10	43	29	34	8
	415	36	39	49	16	8	36	23	23	28
	417	40	36	56	11	4	28	19	18	14
	425	44	30	33	0	5	30	27	25	12
	434	36	61	65	24	10	44	35	28	13
Total		217	271	326	74	46	210	147	140	93
Arithmetic Mean		36.2	45.2	54.3	12.3	7.7	35.0	24.5	23.3	15.5
Geometric Mean			43.4	52.7	9.9	7.3	34.4	23.5	22.2	14.4
B	392	33	1	0	0	0	0	0	0	8
	393	26	3	1	0	0	0	0	1	0
	395	46	2	4	0	0	0	0	3	1
	396	24	0	0	0	0	0	1	1	4
	397	50	17	2	0	0	0	1	8	18
	405	25	0	0	0	0	3	4	15	13
	406	39	3	0	0	0	0	0	1	7
	407	44	15	0	0	0	0	0	19	9
	408	33	12	0	1	0	4	15	16	24
	413	51	8	18	0	0	0	11	1	2
	416	60	7	0	0	0	0	1	7	18
	418	18	4	1	0	0	0	0	12	4
	419	34	16	2	1	0	0	0	1	4
	420	26	4	2	0	0	0	0	3	1
	421	60	2	0	0	0	0	4	21	21
	423	58	3	0	0	0	0	0	3	1
	427	25	3	0	0	1	1	5	10	9
	432	55	10	0	1	1	2	5	8	12
Total		707	110	30	3	2	10	47	130	156
Arithmetic Mean		39.3	6.1	1.7	0.2	0.1	0.6	2.6	7.2	8.7
Artith. % Control			86.5	96.9	98.6	98.6	98.4	89.3	69.0	44.1
Geometric Mean			4.1	0.7	0.1	0.1	0.3	1.2	4.5	5.7
Geom. % Control			90.5	98.7	98.8	98.9	99.1	94.9	79.7	60.4

Table 2. Individual dog and group mean tick (*Rhipicephalus sanguineus*) counts after treatment with RM1601E

GROUP	DOG	Treatment Day								
		-5	1	2	15	22	29	36	43	50
A	410	2	9	8	3	1	0	1	1	1
	414	1	29	44	12	6	7	23	12	1
	415	22	25	49	7	7	13	11	10	8
	417	13	28	24	6	6	14	8	10	3
	425	4	7	8	3	3	1	8	0	2
	434	12	27	39	13	30	18	22	13	7
Total		54	135	172	44	53	53	73	46	22
Arithmetic Mean		9.0	22.5	28.7	7.3	8.8	8.8	12.2	7.7	3.7
Geometric Mean			19.3	22.8	6.4	5.8	5.3	9.1	4.9	2.9
B	392	33	0	0	0	1	0	0	2	1
	393	11	4	2	0	0	0	0	0	1
	395	10	11	2	0	0	0	0	1	0
	396	8	0	1	0	0	0	0	1	1
	397	27	27	6	0	0	0	0	3	3
	405	3	0	1	0	0	1	1	6	2
	406	17	17	0	0	0	0	0	1	0
	407	15	1	0	0	0	0	1	3	2
	408	12	11	0	0	0	0	19	6	5
	413	12	15	20	0	0	0	0	2	1
	416	3	0	0	1	0	0	8	13	6
	418	11	3	0	0	0	1	0	8	1
	419	38	10	3	0	0	0	0	1	1
	420	30	6	5	0	0	0	0	1	1
	421	9	0	0	0	0	0	3	9	4
	423	22	8	0	0	0	0	0	1	0
	427	6	1	0	0	0	0	1	4	1
	432	31	18	4	0	0	1	3	3	0
Total		298	132	44	1	1	3	36	66	30
Arithmetic Mean		16.6	7.3	2.4	0.1	0.1	0.2	2.0	3.7	1.7
Arith. % Control		-	67.4	91.5	99.2	99.4	98.1	83.6	52.2	54.5
Geometric Mean			3.7	1.1	0.0	0.0	0.1	0.8	2.7	1.2
Geom. % Control			80.9	95.2	99.4	99.3	97.7	91.8	46.2	57.4

(4) **Conclusion: Unacceptable.** This study does not support efficacy claims for the proposed product because the average rate tested (8.4 mg fipronil/kg body weight) is higher than the lowest labeled rate (6.0 mg fipronil/kg body weight). In addition, attachment of brown dog ticks in the control treatment is not adequate.

44942105. Dose Titration Study of (S)-Methoprene by Topical Administration to Dogs.

(1) non-GLP, conducted under GCP

(2) **Methods:** This study evaluated the efficacy of an untreated control and four doses (2, 4, 6, and 8 mg s-methoprene/kg body weight) of an s-methoprene spot-on formulation applied to dogs against eggs and emerging

adult cat fleas. Dogs were treated on day 0. Each treatment group contained 6 replicate animals. Dogs were infested with 200 newly emerged adult cat fleas on days -1, 7, 14, 21, 28, 35, 42, 49, and 56. Flea eggs were collected on days 2, 10, 17, 24, 31, 38, 45, 52, and 59. Eggs from each animal on each collection date were divided into two aliquots containing approximately 100 eggs each. Aliquot 1 was used to evaluate larval hatch and aliquot 2 was used to evaluate adult emergence. At 72 hours after egg collections, aliquot 1 was assessed for egg hatch. At 35 days post egg collection, aliquot 2 was assessed for adult emergence.

(3) **Results:** Hatch of flea eggs in the control treatment was between 80-92% for all observation dates. The 2, 4, and 6 mg s-methoprene/kg body weight treatments reduced flea egg hatch by over 90% through the day 28 inoculation. The 8 mg s-methoprene/kg body weight treatments reduced flea egg hatch by over 90% through the day 35 inoculation. Thereafter hatch of flea eggs was reduced by less than 90% through 56 days. The reduction in emergence of adult fleas was similar to the pattern for larval hatch except that the 6 mg s-methoprene/kg body weight treatment reduced adult emergence by over 90% through 35 days post application. Between 60 and 77% emergence of adult fleas was observed in the control group except on days -1, 7, and 21 when 30%, 38%, and 50% emergence was observed respectively.

(4) **Conclusion: Acceptable.** This study supports claims of prevents adult flea emergence, prevents flea egg hatch, and IGR type claims for the proposed product.

44942106. Dose Confirmation Study of Topically Administered Fipronil/ (S)-Methoprene Against Adult *Ctenocephalides felis* (Cat Fleas) in Dogs.

(1) non-GLP, conducted under GCP

(2) **Methods:** This study tested the efficacy of an untreated control, 10% fipronil w/v spot-on formulation (6.7 mg fipronil/kg body weight), 9% s-methoprene w/v spot on formulation (6.0 mg s-methoprene/kg body weight), and a 10% fipronil and 9% s-methoprene combination spot-on product (6.7 mg fipronil/kg body weight and 6.0 mg s-methoprene/kg body weight) against flea eggs, adult, and emerging adult cat fleas. Dogs were treated on day 0. There were eight animals in each treatment group. On days -1, 1, 21, 22, 28, 29, 35, 36, 42, 43, 49, 50, 56, 57, 63, 64, 70, 71, 77, 78, 84, and 85, each animals was inoculated with 200 unfed adult cat fleas. Adulticidal activity was evaluated by comb counts 24 hours post infestation/treatment on days 1, 22, 29, 36, 43, 50, 57, 64, 71, 78, and 85. During the comb counts live fleas were removed from each animal. Flea eggs were collected 72 hours post inoculation (days 4, 25, 32, 39, 46, 53, 60, 67, 74, 81, and 88). Eggs from each animal on each collection date were divided into two aliquots containing approximately 100 eggs each. Aliquot 1 was used to evaluate larval hatch and aliquot 2 was used to evaluate adult emergence. At 72 hours after egg collections, aliquot 1 was assessed for egg hatch. At 35 days post egg collection, aliquot 2 was assessed for adult emergence. Adulticidal activity was also evaluated on fleas inoculated for the purpose of laying flea eggs at 96 h post inoculation (Days 5, 26, 33, 40, 47, 54, 61, 68, 75, 82, and 89). If no eggs were available for an animal, then flea development was not assessed.

(3) **Results:** The s-methoprene-only treatment reduced flea egg hatch and adult emergence by over 90% through 50 days post application. Eggs could not be collected from animals treated with fipronil products until 43 days post application therefore egg hatch and adult emergence could not be assessed during this time frame. Hatch of flea eggs in the control treatment was between 64-85%. When adulticidal efficacy was assessed, the s-methoprene treatment reduced the number of live fleas by between 5 and 24% through 35 days post exposure, but the reduction in the number of live fleas never reached 90%. Both fipronil treatments reduced the number of live fleas by over 95% through 35 days post application. Adult flea reductions were presented as the geometric means, but efficacy is not likely to change if the arithmetic mean is used. In the control treatment, 60-70% of fleas were recovered during comb counts. The mortality of adult fleas assessed at 96 hr post inoculation showed a very similar trend to the fleas assessed 24 hours post inoculation.

(4) **Conclusion: Acceptable.** This study supports claims of kills fleas, prevents adult flea emergence, and IGR type claims for the proposed product.

IV. EXECUTIVE DATA SUMMARY:

(A) The data above support claims of kills/control fleas and flea eggs for up to one month on dogs at the rate of 2 mg s-methoprene/kg body weight. The data also support IGR type claims (e.g., prevents emergence of adult fleas for up to one month) for the proposed product. The Agency does not review data for lice on dogs and cats, therefore, efficacy claims against lice are acceptable.

The data above do not support efficacy claims against ticks because all of the testing was conducted using sprayable products and the Agency does not bridge data collected on sprayable products to support spot-on products. The data also do not support claims against mosquitoes because testing was only conducted with one species, and the test only showed efficacy through 21 days. For spot-on products, all data must show the product to be effective against the target species for the entire month/intended reapplication interval. In addition, for any claims against ticks or mosquitoes, tests need to be conducted on three species of each type of pest. For more information on efficacy testing, including the species required, for ticks and mosquitoes see <https://www.epa.gov/pesticide-registration/guidance-efficacy-testing-pesticides-targeting-certain-invertebrate-pests>. The data also do not support claims of fast acting or claims against mites.

V. LABEL RECOMMENDATIONS:

(1) Please make the following changes to page 2 and the directions for use:

On Page 2 and 18 under Start-back/Side Panel change the paragraph to read as follows: “[Brand Name] [This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to kill fleas.] [The active ingredients in [Brand Name][This product] features a formula developed for control of fleas and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

On Page 4 under Frequency of Application please modify the paragraph to read as follows: “Use [Brand Name] [this product] monthly for control of flea [and] chewing lice infestations. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control chewing lice. [Brand Name] Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].”

In the table of optional graphics on pages 7, 17, and 23, remove the following pets/pest groups and associated graphics from the table:

Flea pupae
Ticks
Brown Dog Tick
Deer Tick
American Dog Tick
Lone Star Tick
Mosquitoes
Mites

On page 12 under “Read Entire Label Before Each Use...8 Weeks of Age” Change the first paragraph and the sentence that follows to read: “[Brand Name] for dogs protects against fleas [and chewing lice]. Stops existing flea infestations for [[4] [four] weeks] [[1] [one] month] [30 days].]

Apply as a [spot] [stripe] to the dog to kill fleas and chewing lice.”

(2) The following marketing claims are acceptable (Bold text indicates section headers on the label):

{Adult Fleas}

[[Kills [adult] Fleas [for up to one month]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once monthly application may be needed. Do not apply more than one a month.]

{Chewing Lice}

[Kills chewing lice]

{Flea Eggs and Larvae}

[Controls flea reinfestation for up to [4 weeks] [1 month]]

[Kills adult fleas, flea eggs, flea larvae for up to [one months] [4 weeks].]

[Controls all stages of the flea (including adult fleas, flea eggs, and flea larvae)]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Prevents from developing, flea eggs [larvae] for up to [1 months] [4 weeks]]

[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle]

[With (S)-methoprene to Break Flea Life Cycle]

[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]

[Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Breaks the Flea Life Cycle]

[Dual Action [!]: Breaks the Flea Life Cycle [!]]

[Kills Flea Eggs & Flea Larvae for [up to 1 months] [up to 4 weeks]!]

[Prevents Flea Eggs From Developing Into Biting Adults]

[Prevents all stages of the flea life cycle from developing]

[Controls reinfestation of fleas for up to 1 months]

[Controls all stages of the flea life cycle]

[Controls all stages of the flea life cycle]

[Prevents reinfestation of listed pests for [4 weeks] [1 month]]

[Stops and prevents infestation of listed pests for [4 weeks][1 month]]

[Stops existing infestation and prevents establishment of additional infestation of listed pests]

(3) The following marketing claims are unacceptable (Bold text indicates section headers on the label):

[Mite Claims]

[Controls] [Aids in the control] [of] [sarcoptic mange infestations]

{Mosquitoes}

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

{Chewing Lice}

[Rapid elimination of chewing lice infestation]

[[A once monthly application required][Apply monthly to control] [for] chewing lice]

{Adult Fleas}

[[Kills [adult] Fleas [for up to three months]]

[If dog is a high risk for flea reinfestation a once month application may be needed]

{Multiple Infestations}

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old [&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]]

[Kills Fleas, Ticks [&] [and] [Mosquitoes]]

[Breaks the Flea Life Cycle [for up to three months]]

[Monthly flea, tick, [mosquito], chewing lice and flea egg protection]

[Monthly flea, tick, [mosquito] and chewing lice protection]

[Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice]

[[Seven] [7] [Six] [6][Five][5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [&][and]flea larvae [&] [and] prevent the development of flea pupae]]

[[Six] [6] [Five] [5][Four][4] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, [&][and]flea eggs [&] [and] flea larvae]

[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]

[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]

[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

[Use [Brand Name]][This product] monthly to control ticks and chewing lice]

[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]
 [Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]
 [Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]
 [Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!]
 [Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]]
{Ticks}
 [Kills Ticks including those that may transmit Lyme disease]
 [Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
 [Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]
 [Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
 [Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks][,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]
 [Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]
{Flea Eggs and Larvae}
 [Controls flea reinfestation for up to [12 weeks] [3 months]]
 [Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae for up to [three months] [12 weeks].]
 [Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
 [Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
 [Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]
 [Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]
 [Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]
 [Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]
 [Controls reinfestation of fleas for up to 3 months]
 [Effective against all stages of the flea life cycle]
 [Effectively controls all stages of the flea life cycle]
 [Fast Acting] [Long Lasting]
 [Best if used year round!]
 [(ICON Showing [4 week] [1 month] [30 day] Protection)]
 [Controls mites that may cause sarcoptic mange]
 [Waterproof]
 [Effective after bathing and exposure to water and sunlight]

(4) The following MRIDs should be removed from the data matrix, as they are classified as “unacceptable” to support the product: 43121114, 43121115, 43121116, 43121117, 43121118, 43121122, 43577712, 45612701, 45620501, 45620502, 45620503, 45620504, 45620505, 45620506, 45866902

(5) Note to RM/PM: The claims section shows up on three times (pages 9/10, 16/17, and 23-25) on the label in different parts, please address the claims in all sections.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

August 4, 2016

MEMORANDUM:

Subject: Name of Pesticide Product: PROMIKA ZOGUARD PLUS FOR DOGS
EPA Reg. No. /File Symbol: 91300-L
DP Barcode: DP 431542
Decision No.: 512125
Action Code: R315
Submission: #978642
E-Sub: #9399
PC Codes: 129121 (Fipronil: 9.8%)
105402 (S-Methoprene: 8.8%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Byron T. Backus
Aug - 4 - 2016

Through: Masih Hashim, Ph.D., Team Leader, Toxicology
CITAB
Registration Division (7505P)

M/Hashim

To: Julie Breeden-Alemi/Kable Davis, RM 03
IVB1
Registration Division (7505P)

Registrant: PROMIKA, LLC

FORMULATION FROM LABEL:

<u>Active Ingredients:</u>	by wt.
129121 Fipronil	9.80%
105402 (S)-methoprene	8.80%
<u>Other Ingredients:</u>	81.40%
TOTAL	100.00%

ACTION REQUESTED: “Please review the 5 cited acute tox studies and the waiver request for acute inhalation to determine acceptability. In addition I have attached copies of the proposed CSF, label and cover letter...”

BACKGROUND: The material available to CITAB includes a data matrix (dated December 10, 2015) for 91300-L with the following acute toxicity and companion animal study citations: MRIDs 44942004 (acute oral toxicity); 44942005 (acute dermal toxicity); 49770003 (acute inhalation toxicity waiver request); 44942006 (primary eye irritation); 44942007 (primary dermal irritation); 44942008 (dermal sensitization); 44942104 (companion animal safety); 45143901 (companion animal safety); 45612702 (companion animal safety); and 45620507 (companion animal safety). In addition, there is a CSF (dated November 20, 2015). The 27-page proposed label indicates (p. 3-4) that this product comes in individual applicators containing 0.023 fl. oz. (0.67 mL) [for dogs weighing 4-22 lbs]; 0.045 fl. oz. (1.34 mL) [23-44 lbs]; 0.091 fl. oz. (2.68 mL) [45-88 lbs]; and 0.136 fl. oz. (4.02 mL) [89-132 lbs]. The label also indicates (p. 11) a multi-dosage unit (“For use only by licensed veterinarians on animals in their control or under their immediate supervision”) designated as **Promika ZoGuard Plus Multi-Dosage for Dogs** containing 0.68 fl. oz. (20.10 mL) which would dispense dosages of 0.67 mL (for dogs weighing 5-22 lbs), 1.34 mL (for dogs weighing 23-44 lbs), 2.68 mL (45-88 lbs), and 4.02 mL (89-132 lbs) and (refer to p. 26 of the proposed label) a product named **Promika ZoGuard Plus for Dogs For Further Labeling and Repackaging Only. Not for Retail Sale or Use with Net Contents: xx gal.**

COMMENTS AND RECOMMENDATIONS:

1. The cited acute toxicity studies (MRIDs 449420-04, -05, -06, -07, and -08) were originally submitted to support the registration of EPA Reg. No. 65331-4, which has a label declaration of Fipronil 9.8% and (S)-Methoprene 11.8%.
2. After a comparison of the CSFs for 91300-L and 65331-4, CITAB concludes that the two formulations are toxicologically similar, and that the acute toxicity studies and companion animal safety studies which supported the registration (and certain label claims) for 65331-4 will also largely support the registration (and certain label claims) for 91300-L. However, because of differences in the inerts CITAB recommends (in lieu of an actual eye irritation study on the formulation for 91300-L) assignment of 91300-L to toxicity category III by that exposure route.

2. The studies in MRIDs 449420-04, -05, -06, -07 and -08 have been previously reviewed (TRB memorandum dated December 12, 1999 for 65331-4). The following is a partial acute toxicity profile for EPA Reg. No. 65331-4 (which would also be appropriate for 91300-L) based on the results of these studies:

Acute oral toxicity	III	Acceptable	MRID 44942004
Acute dermal toxicity	IV	Acceptable	MRID 44942005
Primary eye irritation	III*	Acceptable	MRID 44942006
Primary dermal irritation	IV	Acceptable	MRID 44942007
Dermal sensitization	Negative	Acceptable	MRID 44942008

*Because of differences in the inert CITAB recommends assignment to category III for eye exposure rather than category IV.

3. The material received for 91300-L includes a waiver request (MRID 49770003: Tillman, A. (2015) Promika ZoGuard Plus for Dogs: Waiver Request for Acute Inhalation Toxicity Data. Report No. PR-201505. Unpublished study prepared by Promika, LLC. 6p.), which gives the following argument:

Promika ZoGuard Plus for Dogs is a spot-on product that contains 9.8% fipronil and 8.8% S-methoprene. Due to the use pattern, Promika, LLC requests a waiver from the requirement of acute inhalation data for this product. Inhalation is not expected to be a significant route of exposure. The containers are child resistant packages that contain an applicator which is fully enclosed in a foil backed blister package. Each applicator holds less than 0.15 fluid ounces of formulation (actual contents are 0.023, 0.045, 0.091, or 0.136 fl. oz.). EPA has waived the requirement for inhalation toxicity for similar spot-on products. Therefore, Promika, LLC requests a waiver from the requirement of an acute inhalation study with Promika ZoGuard Plus for Dogs.

The registrant's inhalation waiver request addresses only the use of individual applicators (containing up to 0.136 fl. oz. or 4.02 mL, but according to the proposed label the product would also be available as 1) a 20.10 mL applicator which would dispense a number of doses (up to 0.136 fl. oz or 4.02 mL) and 2) in bulk quantity ("xx gallons") for (possible?) formulation. It is concluded that the potentials for inhalation exposure from the 20.10 mL applicator and bulk quantity package may be considerably more than with the 0.136 fl. oz. (0.5 mL) applicators. In addition, this reviewer has additional concerns which are indicated later in this review.

Based on the registrant's arguments, CITAB concludes that a waiver from the requirement of an inhalation study on this formulation is appropriate **for the applicators (containing up to 0.136 fl. oz. or 4.02 mL only**, with assignment of this product (in the applicators) to toxicity category IV by the inhalation exposure route.

4. Based on the considerations indicated above, the following is the acute toxicity profile for 91300-L (applicators only):

Acute oral toxicity	III	Cited	MRID 44942004
Acute dermal toxicity	IV	Cited	MRID 44942005
Acute inhalation toxicity	IV	Waived	MRID 49769904
Primary eye irritation	III	Cited	MRID 44942006
Primary dermal irritation	IV	Cited	MRID 44942007
Dermal sensitization	Negative	Cited	MRID 44942008

5. Based on the acute toxicity profile given above, the following is the precautionary and first aid labeling for 91300-L (applicators only), as obtained from the Label Review System:

PRODUCT ID #: 091300-00005 [applicators only]

PRODUCT NAME: PROMIKA ZOGUARD PLUS FOR DOGS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

6. The precautionary and first aid statements as proposed by the registrant (for the 0.017 mL applicators) are acceptable.
7. The acute toxicity data requirements for the registration of 91300-L, Promika ZoGuard Plus for Dogs (applicators), have been satisfied.

8. The study in MRID 44942104 (*Nolan-Smith, S. (1999) Fipronil/(S)-Methoprene Topical Solution: Target Species Safety Study in the Dog: Interim Report: Lab Project Number: 1686/2: 1686/2-D1142: PR&D 0002101. Unpublished study prepared by Covance Laboratories Ltd. 266 p. {OPPTS 870.7200}*) was reviewed (TXR 5001488) with the following comments: "Test material was dermally applied at dose levels of 0.133, 0.399 & 0.665 mL/kg to groups of 6M & 6F beagle puppies (52-60 days old at initiation) on Test Days 1 & 29. Controls received no treatment. No significant dose-related effects were noted. Blood samples were not collected at 24 hrs following treatment, as specified by the Guidelines, but remainder of the study generally conformed to Guidelines. Some control and test animals had fecal abnormalities (soft, creamy or mucoid feces) prior to and during the treatment period, possible indications of a parasitic infection. According to report text, puppies had received antihelminthic treatments prior to arrival and had received treatments in the laboratory, but the schedule of treatments is not reported. Because study was still ongoing when this interim report was written, and there is insufficient information relating to the schedule of individual antihelminthic treatments (as well as the material administered for these treatments), the study is currently classified as supplementary."
9. The material in MRID 45143901 (*Nolan-Smith, S. (1999) Fipronil/(S)-Methoprene Topical Solution: Target Species Safety Study in the Dog: Report Amendment: Amendment to Interim Report: Lab Project Number: 1686/2: 1686/2-D1142. Unpublished study prepared by Covance Labs., Ltd. 6 p. {OPPTS 870.7200}*) was used to upgrade the study in MRID 44942104 to acceptable.
10. The study in MRID 45612702 [*Nolan-Smith, S. (2001) To Investigate the Safety of a Topical Formulation Containing ML-2,095,988 509T in Dogs Weighing Approximately 2kg (+/- 1.5kg) at One, Three and Five Times the Maximum Label Recommended Dosage: Final Report: Lab Project Number: 1686/12: 1686/12-D2160: PR&D 0045801. Unpublished study prepared by Covance Laboratories. 324 p.*] was reviewed (TXR 5005723, TRB memorandum dated October 21, 2002) and classified as acceptable with the following comments:

...Frontline Plus (active ingredients: 10% w/v fipronil and 9% w/v {S}-methoprene) was topically applied (between the base of the skull and the shoulder blades at one or more spots) to eight week old dogs weighing less than 11 lbs at 1x, 3x and 5x the prepackaged use (0.67 mL/ puppy) dosage. Forty-eight beagle dogs (24/sex) were randomly allocated to one control and 3 treatment groups with 6 male and 6 female animals in each group. Controls received no treatment. The formulation was delivered from the marketed (0.67 mL) pipettes having 67 mg of fipronil and 60.3 mg of S-methoprene as 1x dosage. Puppies were exposed to the formulation only on Day 1, when they were at an average age of 57 (50 to 63) days and weighed 1.67 to 3.57 kg...

A single topical application of fipronil (10% w/v) and (S)-methoprene (9% w/v) in a solution at 1x, 3x and 5 times the maximum recommended dose, when given to eight week old dogs (approx. 1.5-3.5 kg) showed no treatment related effects.

This study (870-7200) is classified **Acceptable** in demonstrating a 5x margin of safety in dogs 8 weeks old or older...

The study in MRID 45612702 was subsequently used by TRB to set a minimum 5 lb puppy (or dog) body weight, based on the following:

Group mean bodyweights (by sex) are reported on p. 35 of MRID 456127 with individual bodyweights reported on pp. 113-114. Because the Agency has accepted CAS studies with 4 animals/sex/group, the mean weight of the 4 lowest weight (1.80, 2.06, 2.37 and 2.38 kg) males and 4 lowest weight (2.05, 2.20, 2.30 and 2.35 kg) females was calculated. For these 8 puppies the mean weight on day 1 was 2.19 ± 0.21 kg ($=4.83 \pm 0.45$ lbs).

Based on the citation of the study in MRID 45612702 the minimum puppy/dog weight for 91300-L is 5 lbs, and the minimum age is 8 weeks.

11. The study in MRID 45620507 (*Godin, C.; Alva, R. (2000) ML-2,095,988 509T/Dog/Solution/Topical/Safety/Tolerance/Reproduction, Reactions: Final Report: Lab Project Number: PR&D 0020201: WEL 99885: PR&D 00202. Unpublished study prepared by White Eagle Toxicology Laboratory. 123 p.*) was submitted to support the use of EPA Reg. No. 65331-5 on breeding, pregnant and lactating dogs. The study was reviewed (TXR 5008387, TRB memorandum for 65331-5, dated October 21, 2002) with the following comment: The study titled: ““ML-2,095,988 509T/Dog/Solution/Topical/Safety/Tolerance/Reproduction, Reactions” has also been reviewed by TRB. It is concluded that the findings of this study adequately support the proposed use of this product at the label-specified dosage rates on breeding, pregnant and lactating bitches with applications at no less than 28-day intervals (the label specifies 30-day intervals).”
12. The citations to MRIDs 44942104, 45143901 and 45612702 satisfy the companion animal (dog) safety study requirements for the registration of 91300-L. **In addition, based on the citation of the study in MRID 45612702 the minimum puppy/dog weight for 91300-L is 5 lbs, and the minimum age is 8 weeks.** The proposed label indicates (p. 3) a minimum weight of 4 lbs, which has to be revised upwards to 5 lbs. The dosages for 91300-L should be consistent with the accepted dosages for 65331-5 (0.023 fl. oz. or 0.67 mL for 5-22 lbs; 0.045 fl. oz. or 1.34 mL for 23-44 lbs; 0.091 fl. oz. or 2.68 mL for 45-88 lbs; and 0.136 fl. oz. or 4.02 mL for 89-132 lbs).
13. The study in MRID 45620507 would satisfy the use of this product on breeding, pregnant and lactating bitches. However, it is noted that the proposed label for 91300-L does not include this use.

14. According to the proposed label this product would also be available as: 1) a 20.10 mL applicator which would dispense up to 0.136 fl. oz. (4.02 mL) aliquots, and 2) in bulk quantity ("xx gallons") for (possible?) formulation. Neither of these "uses" are present on the label for EPA Reg. No. 65331-5. Both have the potential for increased human applicator exposure which should be reviewed and addressed by HED, particularly as there are concerns regarding the possible formation of (and subsequent human/dog exposure to) the fipronil photodegrate, fipronil desulfinyl, which is more toxic than the parent compound. In addition, the registrant's inhalation acute toxicity data waiver request only addressed the use of this product in applicator tubes, and an inhalation study may be required (particularly for registration of this product in gallon containers).
15. CITAB concludes that 91300-L can be currently registered only as the applicators (which would dispense up to 0.136 fl. oz. or 4.02 mL product).



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

FEE

BARCODE No.: D 431541; **FILE SYMBOL No.:** 91300-L; **PRODUCT NAME:** Promika ZoGuard Plus for Dogs; **DECISION No.:** 512125; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Promika, LLC

This Document Contains Confidential Information

DATE OUT: 06/22/2016

SUBJECT: End Use Product Chemistry Review
Product Name: Promika ZoGuard Plus for Dogs

FROM: Indira Gairola / Product Chemistry Team
CITAB/RD (7505P)

TO: Julie Breeden / Kable Davis, RM 03
I-V Branch 1 / RD (7505P)

1/ 06/23/16
S/Sw 6/27/16

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product Promika ZoGuard Plus for Dogs. In support of the registration application, the registrant is submitting 830 series group A and group B product chemistry data with MRID No's. 497700-01 to -02 along with a revised Basic CSF dated 02/22/16. CITAB has been asked to determine acceptability of the data submitted and the proposed CSF(s).

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s) S-Methoprene (8.8%), Fipronil (9.8%).
2. Has the registrant claimed substantial similarity to a registered product?
☐ Yes; ☒ No; ☐ NA; if yes give the registration number of the cited product. EPA Reg. No.
3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No
4. All inert ingredients have been screened by CITAB (Inert Team) and found to be approved for the proposed label uses - ☒ Yes; ☐ No.

BARCODE No.: D 431541; **FILE SYMBOL No.:** 91300-L; **PRODUCT NAME:** Promika ZoGuard Plus for Dogs; **DECISION No.:** 512125; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Promika, LLC

5. Confidential Statement of Formula(s):

☒ Basic – Dated 11/20/15.

☒ Re-submitted - Dated: 02/22/16

☐ Alternate

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA;

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☐ No; ☒ NA

Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA

Sodium nitrate/sodium nitrite ☐ Yes; ☐ No; ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

BARCODE No.: D 431541; **FILE SYMBOL No.:** 91300-L; **PRODUCT NAME:** Promika ZoGuard Plus for Dogs; **DECISION No.:** 512125; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Promika, LLC

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		x		A	497700-01
830.1600	Description of materials used to produce the product		x		A	497700-01
830.1650	Description of formulation process		x		A	497700-01
830.1670	Discussion on the formation of impurities		x		A	497700-01
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits				CSF dated 02/22/16
		Proposed Limits				
		Justification for wider limits	x		A	
830.1800	Enforcement analytical method ¹		x		A	497700-01 HPLC/UV Details of Validated method were provided

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

1. If validation of analytical method is not provided, the data requirements should be "N" (Not Acceptable)

BARCODE No.: D 431541; **FILE SYMBOL No:** 91300-L; **PRODUCT NAME:** Promika ZoGuard Plus for Dogs; **DECISION No.:** 512125; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Promika, LLC

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Low viscosity liquid	A	497700-02
830.6314	Oxidation/Reduction	The product does not contain any oxidizing or reducing agents	A	497700-02
830.6315	Flammability	Flash point 195°F (90.8°C) (range 194.0-195.8 deg. F)	A	497700-02
830.6316	Explosibility	product does not contain explosive materials	W	
830.7000	pH	7.6 (25 °C; 1% (w/w) aq. (range 7.3-7.9)	A	497700-02
830.7100	Viscosity	6.44 mPa s; 25 °C and 3.81 mPa s; 45°C	A	497700-02
830.7300	Density (units)	1.04 g/mL (@25°C (using pycnometer)	A	497700-02
830.6317	Storage stability Or Accelerated storage stability	Applicant has stated: Will be submitted unless specifically requested by the Agency	G	
830.6320	Corrosion characteristics or Accelerated corrosion characteristics	Applicant has stated: Will be submitted unless specifically requested by the Agency	G	

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

BARCODE No.: D 431541; **FILE SYMBOL No:** 91300-L; **PRODUCT NAME:** Promika ZoGuard Plus for Dogs; **DECISION No.:** 512125; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Promika, LLC

CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the end-use product Tepera Fungicide and has concluded that:

A. Substantial similarity to the cited product (Reg. No) from Product chemistry view point

- ☐ Similar
- ☐ Not similar, give reasons
- ☐ Identical
- ☐ Not identical
- ☒ Not applicable

B. Confidential Statement of formula

Basic CSF (dated 02/22/16)

- ☒ Acceptable
- ☐ Not Acceptable
- ☐ Not Applicable
- If not acceptable provide the reasons
- 1. Alternate CSF (dated)
- ☐ Acceptable -
- ☐ Not Acceptable
- ☒ Not Applicable

If not acceptable give reasons

C. Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of Guideline(s):
- ☐ Not required
- ☐ Data cited

D. Group B Product chemistry data

- ☐ Acceptable
- ☐ Not acceptable
- ☒ Acceptable with the exception of Guideline(s) 830.317& 830.6320 Storage stability& Corrosion Characteristics. These data are a requirement and must be submitted.
- ☐ Not required
- ☐ Data cited

E. Product Label/Draft Label

Recommendations – Yes []; No [x] If yes, give recommendations below.



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WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

See

DP BARCODE No.: D431541; **FILE SYMBOL No.:** 91300-L (screen); **PRODUCT NAME:** Promika ZoGuard Plus For Dogs; **DECISION No.:** 512125; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No

DATE OUT: February 17, 2016

SUBJECT: 45/90 day screen results for end use product "Promika ZoGuard Plus For Dogs"

FROM: Shyam Mathur,
Product Chemistry Team Leader
CITAB / RD (7505P)

SBM

TO: Julie Breeden / Kable Davis, RM 03
I-V Branch 1 / RD (7505P)

Company Name: Promika, LLC
Active Ingredient(s): Fipronil (9.80%) and (s)-Methoprene (8.80%)

MRID No(s): 49770001 to 49770002

CONCLUSION:

Deficiencies: Yes

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required Data submitted

Group B: All required data submitted,

CSF: Basic CSF (Dated 11-20-2015).

Note 1: The proposed CSF must be revised to correct the calculations of nominal concentrations of the AI's. To get the correct NC of 9.80% for the AI fipronil (source AI is [REDACTED] the amount used must be [REDACTED] instead of [REDACTED]. Similarly for the active ingredient Methoprene (source AI is [REDACTED] the amount used must be [REDACTED] instead of [REDACTED]. The amounts of other ingredients must be adjusted accordingly. *J* *SBM*

Draft Product Label: Not Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to author of this report the corrected deficiencies in response to 10 day letter. The corrected information will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

Breeden-Alemi, Julie

From: Roe, Lindsay
Sent: Tuesday, September 20, 2016 11:05 AM
To: Ann Tillman
Cc: Pahel, Lisa; Breeden-Alemi, Julie
Subject: Child Resistant Packaging- 91300-L

Good morning, Ann.

Per our phone call, I am following up with an email describing the issues with the CRP for the Promika ZoGuard for Dogs (single applicator) (EPA Reg # 91300-L).

As agreed previously, the SAUE data for the strips of three will be bridgeable to the single applicator. We feel that during the senior test, a strip of three is equally, if not more, likely to show opening issues or to accidentally expose a user to the pesticide product when compared to a single applicator. The SAUE for the strip of three is adequately protective for users of the single applicator. Data for the small, medium, and large applicators is available in each of the fill volumes proposed for this product.

The Child Resistance Effectiveness test as outlined in the certification letter dated 9/15/2016, however, is not acceptable to cover all of the proposed package sizes. It is the EPA CRP team's position that the way a child manipulates packaging varies between a single applicator and a strip of three applicators, so bridging from the three-strip testing could not be done for this test. In addition, the fact that the small, medium, and large applicators are different packages (different measurements and made in different molds) makes bridging between these different applicators impossible.

Testing has been carried out for the small applicator 0.5 mL fill volume single applicator and the 4.02mL fill volume large single applicator. In order to cover all of the proposed applicator sizes and fill volumes, additional testing would need to be carried out on:

- Medium single applicator 1.34mL and 2.68mL fill volumes
- Large single applicator 1.34mL fill volume (bridging could be used to cover the 2.68mL fill volume of the large single applicator bridging between the 1.34mL and 4.02mL testing)

In short, testing should be carried out at least on the largest and smallest fill volume for each different package.

EPA would accept certifications for these studies as an amendment. The actual study would not need to be submitted, but for each package configuration tested, the certification letter would need to include:

- The product name and EPA registration number
- State whether CRP is voluntary or required for the product
- Identify which package is associated with the CRP test data;
 - o A description of the package tested including a photograph of the package (including closure model and size, material specification, package color, Manufacturer, ASTM classification, size package tested with, and fill volumes);
- The directions on the package used for Senior Adult Use Effectiveness (SAUE) Testing along with any additional directions provided to the Seniors during SAUE Testing
- Since this packaging will be covered by already submitted testing, state that EPA accepted bridging from the 3-strip to the single applicator for the SAUE test and let us know the MRIDs that you are citing to cover this test
- For the CRE Test, state the number of children tested
- Define the number of units that represent a child failure
- State the number of units a child receives at the beginning of the test
- State the number of failures

- The CRP certification statement: I certify that the packaging used for this product meets the standards of 40 CFR 157.32 including the revised standards in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20 as published in 60 FR 37710 (July 21, 1995).
- Sign and date this certification on company letterhead

Under this certification, the studies supporting the packaging configuration must be maintained in your own records, and if the Agency ever needed the study, we could request the study from you.

At this time, the only applicator configurations that could be included on the label are the small applicator with the fill volume of 0.5mL and the large applicator with the fill volume of 4.02mL. References to all other packaging configurations must be removed from all labelling until the CRP certifications amendment is accepted.

The CRP amendment should contain the certification and, if relevant, a label revised to include references to the package configurations being added.

If you have any additional questions or if anything is unclear, please feel free to contact me.

Best regards,
Lindsay

Lindsay Roe - EPA/OCSP - Office of Pesticide Programs - Registration Division, Fungicide Branch
Roe.lindsay@epa.gov
(703) 347-0506

**Child Resistant Packaging Certification
For Promika ZoGuard Plus for Dogs (single applicator)
(EPA Registration No. 91300-L)**

Registrant: Promika, LLC
501 Cascade Pointe Lane, Suite 102
Cary, NC 27513

I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32.

EPA Registration No. 91300-L, Promika ZoGuard Plus for Dogs, is **filled and packaged by Firma Klocke Verpackungs-Service GmbH**. The package (see photo, attached) consists of a placebo filled applicator with a clear plastic front and white foil backing. The clear plastic front lidding is constructed of PET/OPA/ALU/HDPE – 23/25/9/50 μm and the forming material for the applicator is CPA/PP/COC/HDPE – 50/100/380/50 μm. The applicator is the child-resistant packaging. The applicator has three applicator bulb sizes: small, medium and large. The small applicator fill level is 0.67 mL. The medium applicator fill levels are 1.34 mL and 2.68 mL. The large applicator fill levels are 1.34, 2.68, and 4.02 mL. Child Resistant Packaging, CRP, testing was conducted on one applicator with a placebo filled applicator bulb at two fill levels:

- 0.136 fl. oz. (4.02 mL; large bulb) MRID 49794001
- 0.017 fl. oz. (0.5 mL) MRID 49794001

The following SAUE data can be used to support the CRP for different fill volumes for the small, medium and large applicator sizes for a strip of 3 (or 4 where noted) blisters attached to each other:

- 0.017 fl. oz. (0.5 mL; small bulb) MRID 49649301
- 0.023 fl. oz. (0.67 mL; small bulb) MRID 49649302
- 0.023 fl. oz. (0.67 mL; small bulb) MRID 49649308
- 0.0135 fl. oz. (0.4 mL; small bulb) MRID 49681401 (two strips of 3)
- 0.0078 fl. oz. (0.23 mL; small bulb) MRID 49719401 (one strip of 4)
- 0.017 fl. oz. (0.5 mL; small bulb) MRID pending for study number KVS/201522
- 0.034 fl. oz. (1.0 mL; medium bulb) MRID 49649309
- 0.045 fl. oz. (1.34 mL; medium bulb) MRID 49649303
- 0.091 fl. oz. (2.68 mL; medium bulb) MRID 49649304
- 0.045 fl. oz. (1.34 mL; large bulb) MRID 49649306
- 0.0845 fl. oz. (2.5 mL; large bulb) MRID 49649310
- 0.091 fl. oz. (2.68 mL; large bulb) MRID 49649307
- 0.135 fl. oz. (4.0 mL; large bulb) MRID 49681402 (two strips of 3)
- 0.135 fl. oz. (4.0 mL; large bulb) MRID 49719402 (one strip of 4)
- 0.136 fl. oz. (4.02 mL; large bulb) MRID 49649305

I realize that additional CRP testing may be required if EPA Registration No. 91300- , Promika ZoGuard Plus for Dogs is **not filled and packaged by Firma Klocke Verpackungs-Service GmbH on the same equipment as the samples tested**. Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for EPA Registration No. 91300- , Promika ZoGuard Plus for Dogs.

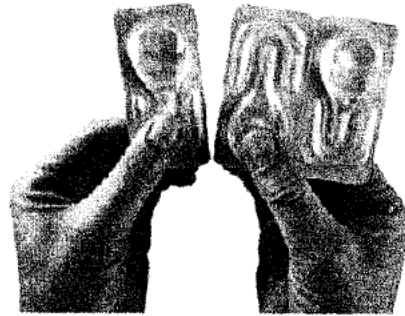
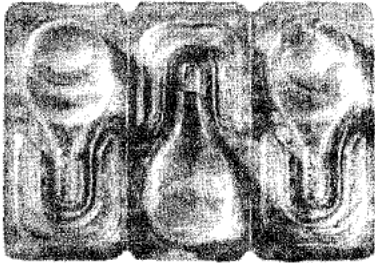


Ann M. Tillman
Agent for Promika, LLC
Pyxis Regulatory Consulting, Inc.

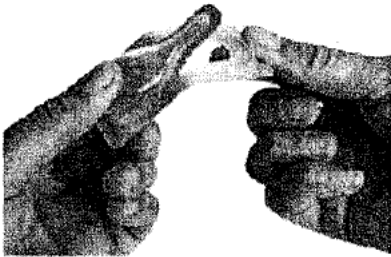
Sept. 15, 2016
Date

Child Resistant Packaging Certification
For Promika ZoGuard Plus for Dogs (single applicator)
(EPA Registration No. 91300-L)

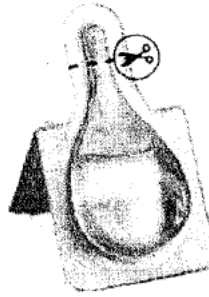
1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator



**Child Resistant Packaging Certification
For Promika ZoGuard Plus for Dogs (Strip of 3)
(EPA Registration No. 91300-L)**


Registrant: Promika, LLC
501 Cascade Pointe Lane, Suite 102
Cary, NC 27513

I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32.

EPA Registration No. 91300-L, Promika ZoGuard Plus for Dogs is **filled and packaged by Firma Klocke Verpackungs-Service GmbH or by Klocke of America**. The package (see photo, attached) consists of a placebo filled applicator with a clear plastic front and foil backing that is contained in a blister. The blister has a clear plastic front (PET/PP/PE transp. LDPE – 350/100/75) and a foil backing (PET/AL/PET/PE – 12/12/12/75). Three blisters are connected to each other. The applicator is the child-resistant packaging. The applicator has four fill levels, which are 0.023 fl. oz. (0.67 mL), 0.045 fl. oz. (1.34 mL), 0.091 fl. oz. (2.68 mL) and 0.136 fl. oz. (4.02 mL). Child Resistant Packaging, CRP, testing was conducted on the blister with a placebo filled applicator at each of the four fill levels. References for these tests are as follows:

- MRID No. 48703501 (also submitted under MRID 48652814), 48703502 (also submitted under MRID 48652854), 48703503 (also submitted under MRID 48652816), 48652701 (KVS studies) 0.67 mL adult+child 1.34 mL adult+child
- MRID No. 49179701 (KOA study) 4.02 mL adult+child
- MRID No. 49179702 (Comparison of KVS and KOA studies) 2.68 mL adult+child
- MRID No. 48703504 (Summary data for KVS studies)
- MRID No. 49179703 (Summary data for KOA studies)

I realize that additional CRP testing may be required if EPA Registration No. 91300-L, Promika ZoGuard Plus for Dogs is **not filled and packaged by Firma Klocke Verpackungs-Service GmbH or by Klocke of America on the same equipment as the samples tested**. Further, any change in CRP opening instructions from those used in testing, size, and/or materials for the CRP may result in additional CRP testing for Promika ZoGuard Plus for Dogs, EPA Registration No. 91300-L.



Ann M. Tillman
Agent for Promika, LLC
Pyxis Regulatory Consulting, Inc.

Sept.15, 2016
Date

**Child Resistant Packaging Certification
For Promika ZoGuard Plus for Dogs (Strip of 3)
(EPA Registration No. 91300-L)**

How to Use:

REMOVE AND OPEN PACKAGE

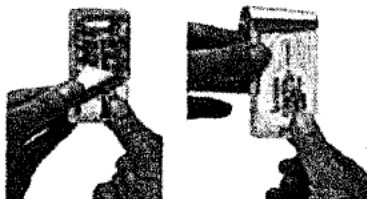
- 1.** Cut along scissor cut line to separate unit



- 2.** Turn unit over and cut corner at bulb end



- 3.** From cut corner, peel backing completely off from bottom to top



- 4.** Remove the applicator



OPEN APPLICATOR

Hold upright with foil side away from you and snap applicator tip back to open.

**Child Resistant Packaging Certification
For Promika ZoGuard Plus for Dogs
(EPA Registration No. 91300-)**

Registrant: Promika, LLC
1204 Village Market Place, #273
Morrisville, NC 27560

I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32.

EPA Registration No. 91300- , Promika ZoGuard Plus for Dogs is **filled and packaged by Firma Klocke Verpackungs-Service GmbH or by Klocke of America**. The package consists of a placebo filled pipette with a clear plastic front and foil backing that is contained in a blister. The blister has a clear plastic front (PET/PP/PE transp. LDPE – 350/100/75) and a foil backing (PET/AL/PET/PE – 12/12/12/75). Three blisters are connected to each other. The blister is the child-resistant packaging. The pipette has four fill levels, which are 0.023 fl. oz. (0.67 mL), 0.045 fl. oz. (1.34 mL), 0.091 fl. oz. (2.68 mL) and 0.136 fl. oz. (4.02 mL). Child Resistant Packaging, CRP, testing was conducted on the blister with a placebo filled pipette at each of the four fill levels. References for these tests are as follows:

- MRID No. 48703501 (also submitted under MRID 48652814), 48703502 (also submitted under MRID 48652854), 48703503 (also submitted under MRID 48652816), 48652701 (KVS studies)
- MRID No. 49179701 (KOA study)
- MRID No. 49179702 (Comparison of KVS and KOA studies)
- MRID No. 48703504 (Summary data for KVS studies)
- MRID No. 49179703 (Summary data for KOA studies)

I realize that additional CRP testing may be required if EPA Registration No. 91300- , Promika ZoGuard Plus for Dogs is **not filled and packaged by Firma Klocke Verpackungs-Service GmbH or by Klocke of America on the same equipment as the samples tested**. Further, any change in CRP opening instructions from those used in testing, size, and/or materials for the CRP may result in additional CRP testing for Promika ZoGuard Plus for Dogs, EPA Registration No. 91300- .



Ann M. Tillman
Agent for Promika, LLC
Pyxis Regulatory Consulting, Inc.

Dec. 2, 2015
Date

DOCUMENTUM

**Child Resistant Packaging Certification
For Promika ZoGuard Plus for Dogs (single applicator)
(EPA Registration No. 91300-)**

Registrant: Promika, LLC
1204 Village Market Place, #273
Morrisville, NC 27560

I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32.

EPA Registration No. 91300- , Promika ZoGuard Plus for Dogs, is **filled and packaged by Firma Klocke Verpackungs-Service GmbH**. The package consists of a placebo filled applicator with a clear plastic front and white foil backing. The clear plastic front lidding is constructed of PET/OPA/ALU/HDPE – 23/25/9/50 µm) and the forming material for the applicator is CPA/CPP/COC/HDPE – 50/100/380/50 µm. The applicator is the child-resistant packaging. The applicator has three applicator bulb sizes: small, medium and large. The small applicator fill level is 0.67 mL. The medium applicator fill levels are 1.34 mL and 2.68 mL. The large applicator fill levels are 1.34, 2.68, and 4.02 mL. Child Resistant Packaging, CRP, testing was conducted on one applicator with a placebo filled applicator bulb at various fill levels.

- 0.136 fl. oz. (4.02 mL; large bulb) MRID pending (study number KVS201523)

The following data support the CRP for different fill volumes for the small, medium and large applicator sizes for a strip of 3 (or 4 where noted) blisters attached to each other:

- 0.017 fl. oz. (0.5 mL; small bulb) MRID 49649301
- 0.023 fl. oz. (0.67 mL; small bulb) MRID 49649302
- 0.023 fl. oz. (0.67 mL; small bulb) MRID 49649308
- 0.0135 fl. oz. (0.4 mL; small bulb) MRID 49681401 (two strips of 3)
- 0.0078 fl. oz. (0.23 mL; small bulb) MRID 49719401 (one strip of 4)
- 0.017 fl. oz. (0.5 mL; small bulb) MRID pending for study number KVS/201522
- 0.034 fl. oz. (1.0 mL; medium bulb) MRID 49649309
- 0.045 fl. oz. (1.34 mL; medium bulb) MRID 49649303
- 0.091 fl. oz. (2.68 mL; medium bulb) MRID 49649304
- 0.045 fl. oz. (1.34 mL; large bulb) MRID 49649306
- 0.0845 fl. oz. (2.5 mL; large bulb) MRID 49649310
- 0.091 fl. oz. (2.68 mL; large bulb) MRID 49649307
- 0.135 fl. oz. (4.0 mL; large bulb) MRID 49681402 (two strips of 3)
- 0.135 fl. oz. (4.0 mL; large bulb) MRID 49719402 (one strip of 4)
- 0.136 fl. oz. (4.02 mL; large bulb) MRID 49649305

I realize that additional CRP testing may be required if EPA Registration No. 91300- , Promika ZoGuard Plus for Dogs is **not filled and packaged by Firma Klocke Verpackungs-Service GmbH on the same equipment as the samples tested**. Further, any change in CRP opening instructions from those used in testing, color, size, and/or materials for the CRP may result in additional CRP testing for EPA Registration No. 91300- , Promika ZoGuard Plus for Dogs.



Ann M. Tillman
Agent for Promika, LLC
Pyxis Regulatory Consulting, Inc.

Dec. 2, 2015
Date



KLOCKE OF AMERICA, INC.
INNOVATIVE PACKAGING SOLUTIONS

Kable Davis
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

October 7, 2015

Re: Letter of Authorization

Dear Sir,

Please let this letter serve to notify you that Promika, A CSE Life Science Company located at 1204 Village Market Place, #273, Morrisville, NC 27560 is authorized to submit or rely upon the following CRP data in support of its application for registration of ZoGuard Plus for Cats, ZoGuard Plus for Dogs, and VectaShield Complete for Dogs, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.:

49179701	Volume 1	US 16 CFR § 1700	Novosad, M. Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201302. May 16, 2013 (Child 12-068, 13-018; Adult 12-069, 13-018).
49179702	Volume 2	US 16 CFR § 1700	Tillman, A. M. Overview of Child Resistant Packaging Studies: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201303. June 11, 2013.
49179703	Volume 3	US 16 CFR § 1700	Novosad, M. Child Resistant Packaging Test Summary Report: Thermoforme Blister Pack for Pipettes of 0.5 mL, 0.67 mL and 4.02 mL Capacity. Report Number KOA-201301. May 16, 2013 (Child 12-068, 13-018; Adult 12-069, 13-018).

Klocke of America, Inc. owns the above listed data and submission by Promika does not confer ownership rights of these data; other companies may rely on these data without compensation to Promika.

Please feel free to contact me should there be any questions.

Sincerely,

Mr. Donald W. Hopta
CEO and Corporate V.P.
Klocke of America, Inc.

14201 Jetport Loop, Fort Myers, FL 33913-7713
phone 239.561.5800 fax 239.561.5811
website www.klockeamerica.com email packaging@klockeamerica.com

DOCUMENTUM



KLOCKE VERPACKUNGS-SERVICE GMBH

Klocke Verpackungs-Service GmbH Postfach 1140 D-76352 Weingarten

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U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
Arlington, VA 22202

Telefon-Nr.: 07244/61-1430
Fax: 07244/61-2500
E-Mail-Adresse: Matthias.Linder@klocke.com
Ansprechpartner: Matthias LINDER
Datum: 2015-11-25

Re: Letter of Authorization

Dear Sir,

Please let this letter serve to notify you that Promika, LLC. A CSE Life Science Company located at 1204 Village Market Place, #273, Morrisville, NC 27560 is authorized to submit or rely upon the following CRP data in support of its application for registration of Promika ZoGuard Plus for Cats, Promika ZoGuard Plus for Dogs and VectaShield Complete for Dogs, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.

48652603	Novosad, M. (2011) Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.5 mL Capacity. Project Number: KVS/201101. Unpublished study prepared by National Child Resistant Testing, Inc. 16p.
48771101	Novosad, M. (2011) Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.5mL Capacity. Project Number: KVS/201106. Unpublished study prepared by National Child Resistant Testing, Inc. 16p.
48755301	Novosad, M. (2011) Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.5mL Capacity. Project Number: KVS/201106. Unpublished study prepared by National Child Resistant Testing, Inc. 16p.
48703501	Novosad, M. (2011) (Zeronil Spot-On Solution for Dogs): Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 0.67 mL Capacity: (Final Report). Project Number: KVS/201107. Unpublished study prepared by National Child Resistant Testing, Inc. 16p.
48703502	Novosad, M. (2011) (Zeronil Spot-On Solution for Dogs): Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 1.34mL Capacity: (Final Report). Project Number: KVS/201108. Unpublished study prepared by National Child Resistant Testing, Inc. 16p.
48703503	Novosad, M. (2011) (Zeronil Spot-On Solution for Dogs): Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 4.02mL Capacity: (Final Report). Project Number: KSV/201109. Unpublished study prepared by National Child Resistant Testing, Inc. 16p.
48703504	Novosad, M. (2011) (Zeronil Spot-On Solution for Dogs): Child Resistant Packaging Test Summary Report: Thermoforme Blister Pack for Pipettes of 0.5mL Capacity, 0.67mL Capacity, 1.34mL Capacity, 2.68mL Capacity, 4.02mL Capacity: (Final Report). Project Number: KVS/201110. Unpublished study prepared by National Child Resistant Testing, Inc. 17p.
48652701	Novosad, M. (2011) Child Resistant Packaging Study: Thermoforme Blister Pack for Pipettes of 2.68mL Capacity. Project Number: KVS/201104. Unpublished study prepared by National Child Resistant Testing, Inc. 16p.

Klocke
Verpackungs-Service GmbH
Max-Becker-Str. 6
D-76356 Weingarten
Fon: 07244/61-0
Fax: 07244/61-1170
Internet: www.klocke.com

Bankverbindungen:
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IBAN: DE81660202860352955442, SWIFT (BIC): HYVEDEMM475
Volksbank Stutensee-Weingarten eG, BLZ 66061724, Kto.-Nr. 30218000
IBAN: DE03660617240030218000, SWIFT (BIC): GENODE61WGA
BW Bank, BLZ 60050101, Kto.-Nr. 4022675
IBAN: DE90600501010004022675, SWIFT (BIC): SOLADEST
Banque Palatine
IBAN: FR7740978000590375033R00148, SWIFT (BIC): BSPFFRPPXXX

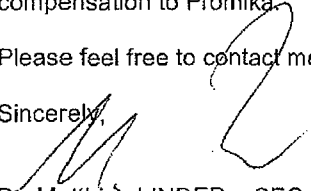
Geschäftsführer:
Carsten Klocke / Dr. Matthias Linder
Erfüllungsort: Weingarten/Baden
Gerichtsstand Karlsruhe
Registergericht: Amtsgericht
Mannheim HRB 105401
Ust-Id-Nr.: DE143584384
Steuer-Nr.: 34423/20401

DOCUMENTUM

KLOCKE VERPACKUNGS-SERVICE GMBH owns the above listed data and submission by Promika does not confer ownership rights of these data; other companies may rely on these data without compensation to Promika.

Please feel free to contact me should there be any questions.

Sincerely,


Dr. Matthias LINDER – CEO
Klocke Verpackungs-Service GMBH

Cc: Promika, LLC

Klocke
Verpackungs-Service GmbH
Max-Becker-Str. 6
D-76356 Weingarten
Fon: 07244/61-0
Fax: 07244/61-1170
Internet: www.klocke.com

Bankverbindungen:
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IBAN: DE90600501010004022675, SWIFT (BIC): SOLADEST
Banque Paribas
IBAN: FR7740978000590375033R00148, SWIFT (BIC): BSPFFRPPXXX

Geschäftsführer:
Carsten Klocke / Dr. Matthias Linder
Erfüllungsort: Weingarten/Baden
Gerichtsstand Karlsruhe
Registergericht: Amtsgericht
Mannheim HRB 105401
Ust-Id-Nr.: DE143584364
Steuer-Nr.: 34423/20401



KLOCKE VERPACKUNGS-SERVICE GMBH

Klocke Verpackungsservice GmbH, Postfach 10, D-76356 Weingarten

Kable Davis
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
Arlington, VA 22202

Phone-No.: 07244/61-1430
EMail-adress: matthias.linder@klocke.com

Contact: Dr. Matthias Linder
Date: 14th December 2015

Letter of Authorization

Dear Sir,

Klocke Verpackungs-Service GMBH (Klocke), Max-Becker-Str. 6, D-76356 Weingarten, Baden, Germany was the sponsor of certain CRP data. Klocke Verpackungs-Service GMBH owns the data listed in Exhibit A which will be submitted to EPA in support of Promika, LLC's application for registration of Promika ZoGuard Plus for Cats, Promika ZoGuard Plus for Dogs and VectaShield Complete for Dogs.

This letter serves to notify you that Klocke Verpackungs-Service GMBH (Klocke) hereby authorizes the U. S. Environmental Protection Agency to allow Promika LLC (EPA Co. No. 91300) to cite the Klocke data listed in Exhibit A in support of their application for registration of Promika ZoGuard Plus for Cats, Promika ZoGuard Plus for Dogs and VectaShield Complete for Dogs, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.

This authorization is qualified to the extent that:

- 1) Neither the applicant nor any other person, except the Agency, shall have access to said data unless specifically authorized in writing by Klocke;
- 2) This authorization does not confer ownership or exclusive rights of the data;
- 3) This authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any subsequent applications with the exception of any amendment to Promika, LLC's registration(s); and
- 4) This authorization shall not be transferred by the applicant in any manner whatsoever without express prior consent of Klocke.

Inasmuch as Klocke is aware of the subject application per 40 CFR 152.116(c) and does not object to the issuance of the registration, the Agency does not need to provide Klocke with the 30-day notification described in paragraph (a) of 40 CFR 152.116.

Klocke
Verpackungs-Service GmbH
Max-Becker-Str. 6
D-76356 Weingarten
Fon: 07244/61-0
Fax: 07244/61-1170
Internet: www.klocke.com

Bank Account:
HypoVereinsbank Karlsruhe, BLZ 65020286, Kto.-Nr. 352955442
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IBAN: DE03660617240030218000, SWIFT (BIC): GENODE31WGA
BW Bank, BLZ 60050101, Kto.-Nr. 4022675
IBAN: DE90600501010004022675, SWIFT (BIC): SOLADEST
Banque Palatine
IBAN: FR7740978000590375033R00148, SWIFT (BIC): BSPFFRPPXXX

Chief Executive Director:
Carsten Klocke / Dr. Matthias Linder
Place of fulfillment: Weingarten/Baden
Place of jurisdiction: Karlsruhe
Registration court: district
Mannheim HRB 105401
VAT-ID-no.: DE143584364
Tax no: 34423/20401

DOCUMENTUM

If you have any questions, please contact our agent, Janelle Kay, Pyxis Regulatory Consulting, Inc. at (253) 853-7369 (Janelle@PyxisRC.com).

Sincerely,



Dr. Matthias Linder, Managing Director
Klocke Verpackungs-Service GmbH
Max-Becker Str. 6
D-76256 Weingarten
Germany
Tel: 49 (7805) 401 115

cc: Brooke Hedrick - Regulatory Manager and Project Management
Promika, LLC

Attachment: Exhibit A

Klocke
Verpackungs-Service GmbH
Max-Becker-Str. 6
D-76256 Weingarten
Fon: 07244/61-0
Fax: 07244/61-1170
Internet: www.klocke.com

Bank Account:
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IBAN: DE81660202860352955442, SWIFT (BIC): HYVEDEMM475
Volksbank Stutensee-Weingarten eG, BLZ 66061724, Kto.-Nr. 30218000
IBAN: DE03660617240030218000, SWIFT (BIC): GENODE61WGA
BW Bank, BLZ 60050101, Kto.-Nr. 4022875
IBAN: DE90600501010004022875, SWIFT (BIC): SOLADEST
Banque Palatine
IBAN: FR7740978000590375033R00148, SWIFT (BIC): BSPFFRPPXXX

Chief Executive Director:
Carsten Klocke / Dr. Matthias Linder
Place of fulfillment: Weingarten/Baden
Place of jurisdiction Karlsruhe
Registration court: district
Mannheim HRB 105401
VAT-ID-no.: DE143584364
Tax no: 34423/20401

EXHIBIT A

MRID	Citation	Description
49649313	KVS/201503	Tillman, A. (2015) Child Resistant Packaging with Thermoform Applicators of Various Fill Sizes: Summary and Request for Bridging Data. Project Number: KVS/201513, KVS/201501, KVS/201502. Unpublished study prepared by Klocke Verpackungs-Service GmbH. 17p.
49649301	KVS/201501	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator of 0.5 mL Capacity. Project Number: KVS/201501. Unpublished study prepared by National Child Resistant Testing, Inc. 14p.
49649302	KVS/201502	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator of 0.67 mL Capacity. Project Number: KVS/201502. Unpublished study prepared by National Child Resistant Testing, Inc. 14p.
49649303	KVS/201503	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator (Medium) of 1.34 mL Capacity. Project Number: KVS/201503. Unpublished study prepared by National Child Resistant Testing, Inc. 14p.
49649304	KVS/201504	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator (Medium) of 2.68 mL Capacity. Project Number: KVS/201504. Unpublished study prepared by National Child Resistant Testing, Inc. 14p.
49649305	KVS/201505	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator of 4.02 mL Capacity. Project Number: KVS/201505. Unpublished study prepared by National Child Resistant Testing, Inc. 14p.
49649306	KVS/201506	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator (Large) of 1.34 mL Capacity. Project Number: KVS/201506. Unpublished study prepared by National Child Resistant Testing, Inc. 14p.
49649307	KVS/201507	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator (Large) of 2.68 mL Capacity. Project Number: KVS/201507. Unpublished study prepared by National Child Resistant Testing, Inc. 14p.
49649308	KVS/201508	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator of 0.23 mL Capacity. Project Number: KVS/201508. Unpublished study prepared by National Child Resistant Testing, Inc. 14p.
49649309	KVS/201509	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator of 1.0 mL Capacity. Project Number: KVS/201509. Unpublished study prepared by National Child Resistant Testing, Inc. 10p.
49649310	KVS/201510	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator of 2.5 mL Capacity. Project Number: KVS/201510. Unpublished study prepared by National Child Resistant Testing, Inc. 10p.
49649311	KVS/201511	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator of 6.0 mL Capacity. Project Number: KVS/201511. Unpublished study prepared by National Child Resistant Testing, Inc. 10p.
49649312	KVS/201512	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator of 6.0 mL Capacity. Project Number: KVS/201512. Unpublished study prepared by National Child Resistant Testing, Inc. 14p.
49681401	KVS/201514	Novosad, C. Child Resistant Packaging Study. Thermoforme Applicator of 0.4 mL Capacity. KVS-201514.
49681402	KVS/201515	Novosad, C. Child Resistant Packaging Study. Thermoforme Applicator of 4.0 mL Capacity. KVS-201515.
49681403	KVS/201516	Tillman, A. M. Child Resistant Packaging with Thermoform Applicators of Various Fill Sizes: Summary and Request for Bridging of Data to Allow Additional Retail Packaging. KVS-201516.
49719401	KVS/201517	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator of 0.23 mL Capacity. Project Number: KVS/201517. Unpublished study prepared by National Child Resistant Testing, Inc. 16p.
49719402	KVS/201518	Novosad, C. (2015) Child Resistant Packaging Study: Thermoforme Applicator of 4.0 mL Capacity. Project Number: KVS/201518. Unpublished study prepared by National Child Resistant Testing, Inc. 15p.
49719403	KVS/201521	Tillman, A. (2015) Child Resistant Packaging with Thermoform Applicators of Various Fill Sizes: Summary and Request for Bridging of Data to Allow Additional Retail Packaging. Project Number: KVS/201521. Unpublished study prepared by Klocke Verpackungs-Service GmbH. 18p.

Klocke
Verpackungs-Service GmbH
Max-Becker-Str. 6
D-76356 Weingarten
Fon: 07244/61-0
Fax: 07244/61-1170
Internet: www.klocke.com

Bank Account:
HypoVereinsbank Karlsruhe, BLZ 66020286, Kto.-Nr. 352955442
IBAN: DE81600202860352955442, SWIFT (BIC): HYVEDEMM475
Volksbank Stutensee-Weingarten eG, BLZ 66061724, Kto.-Nr. 30218000
IBAN: DE03660617240030218000, SWIFT (BIC): GENODE61WGA
BW Bank, BLZ 60050101, Kto.-Nr. 4022675
IBAN: DE90600501010004322675, SWIFT (BIC): SOLADEST
Banque Palatine
IBAN: FR7740978000590375033R00148, SWIFT (BIC): BSPFFRPPXXX

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Place of fulfillment: Weingarten/Baden
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Mannheim HRB 105401
VAT-ID-no.: DE143584364
Tax no: 34423/20401

MRID	Citation	Description
	KVS-201522	Novosad, C. Child Resistant Packaging Study. Thermoforme Applicator of 0.5 mL Capacity. KVS-201522.
	KVS-201523	Novosad, C. Child Resistant Packaging Study. Thermoforme Applicator of 4.02 mL Capacity. KVS-201523.

Klocke
Verpackungs-Service GmbH
Max-Becker-Str. 6
D-76356 Weingarten
Fon: 07244/61-0
Fax: 07244/61-1170
Internet: www.klocke.com

Bank Account:
HypoVereinsbank Karlsruhe, BLZ 66020286, Kto.-Nr. 352955442
IBAN: DE81660202860352955442, SWIFT (BIC): HYVEDEMM475
Volksbank Stutensee-Weingarten eG, BLZ 66061724, Kto.-Nr. 30218000
IBAN: DE03660617240030218000, SWIFT (BIC): GENODE61WGA
BW Bank, BLZ 60050101, Kto.-Nr. 4022675
IBAN: DE90600501010004022675, SWIFT (BIC): SOLADEST
Banque Palatine
IBAN: FR7740978000590375033R00148, SWIFT (BIC): BSPFFRPPXXX

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Mannheim HRB 105401
VAT-ID-no.: DE143584364
Tax no: 34423/20401

Breeden-Alemi, Julie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Monday, October 03, 2016 11:24 AM
To: Breeden-Alemi, Julie
Subject: RE: EPA File Symbol 91300-L
Attachments: 091300-L 20160929 Promika ZoGuard Plus Dogs Label.pdf

Resub

Julie,

Label with text moved (to page 8) is attached.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: October 03, 2016 10:26 AM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: RE: EPA File Symbol 91300-L

Good morning Ann,

I hope you had an enjoyable weekend. I have a quick question of clarification for you. Do you have time for a phone call? It will probably take 5 minutes or less. My question in regards to page 4 of the dog label.

Thank you,
 Julie

Julie A. Breeden-Alemi, DVM
 U.S. Environmental Protection Agency
 OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
 Phone: 703.347.0511

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Thursday, September 29, 2016 4:43 PM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Resub

Julie,

Changes were made....

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: September 29, 2016 3:18 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Hi Ann,

Attached are a few label comments. I am out of the office tomorrow, but if you send the revised labels, I'll attend to them first thing Monday morning. Please call if you have questions. I'm in the office until 4:30pm today.

Thank you,
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Ann Tillman [<mailto:Ann@PyxisRC.com>]
Sent: Wednesday, September 28, 2016 2:29 PM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Julie,

The revised dog labels are attached.

Ann

From: Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]
Sent: September 27, 2016 4:28 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Hi Ann,

Attached are label comments. If you want to touch base by phone for clarification of anything before sending revised labels, you can reach me tomorrow between 6-9am and 1-2pm. I'll also be in the office on Thursday and the following Monday.

Thanks so much,
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Breeden-Alemi, Julie
Sent: Thursday, September 22, 2016 4:43 PM

To: 'Ann Tillman' <Ann@PyxisRC.com>

Subject: RE: EPA File Symbol 91300-L

Ann,

I've already talked to PMs about this, but I am meeting with Bo again on Monday, and I'll bring this concern up again for discussion. I'll be in touch on Monday.

Enjoy your weekend,
Julie

From: Ann Tillman [mailto:Ann@PyxisRC.com]

Sent: Thursday, September 22, 2016 11:59 AM

To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>

Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>

Subject: RE: EPA File Symbol 91300-L

Julie,

Is there a reason why other registrants are allowed to have optional language for applying the same product (i.e., page 3 of the label)? See, for example, labels for 53883-351 and 2517-134)? The text below is what I propose. Is this text acceptable?

Apply one applicator (1.34 mL)(0.045 fl oz)

[evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply any excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.] {OR}
[as a spot [on] [to] the dog's back between the shoulder blades.]

The Warranty statement is meant to be optional text.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]

Sent: September 21, 2016 4:22 PM

To: Ann Tillman <Ann@PyxisRC.com>

Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>

Subject: RE: EPA File Symbol 91300-L

Hi Ann,

Please find attached label comments for File Symbol 91300-L, Promika ZoGuard for Dogs as well as a Pre-Decisional letter.

Regarding the "Insert" for Sublabel 2:

Ideally, we are requesting full-label text (all text as found on the foil pouch itself plus that currently indicated as on the insert).

At minimum we request a complete set of Directions for Use plus the text currently indicated as on the insert.

If you'd like to discuss for clarification, please feel free to call.

Enjoy your afternoon,
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Ann Tillman [<mailto:Ann@PyxisRC.com>]
Sent: Tuesday, September 20, 2016 2:27 PM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Julie,

At this point, we will change to "vials". The Side Effects language came from labels for 53883-352 and 53883-351.

Ann

From: Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]
Sent: September 20, 2016 11:45 AM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Thank you, Ann for your response.

Tube/Vial:

What I am understanding is that currently the term "vial" is most accurate with regard to submitted CRP. In the future, amendments will be submitted changing the CRP which at that time will more accurately reflect the term "tube." Can we not use the term vial now and with the future amendments change it to tube?

Side Effects:

I have the submitted labels, cited labels, and mitigation before me at all times. This is why I'm asking the question. The mitigation proposes language. The cited label has differing language. Your labels have language that differs from the cited labels and the mitigation. I am trying to work with the text that you proposed, but I have to ask where some of the text came from because it is different from the cited labels and mitigation.

I did make a comment about GI signs missing in the Side Effects box: The side effects language doesn't include any mention of possible gastrointestinal signs such as vomiting or diarrhea as noted in the mitigation. Can you please comment? I did not propose an exact sentence. I do not know where the exact sentence added came from, therefore, I am asking.

Another example, "The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours." Where is this text coming from? And so on.

Understanding the background for these statements will help navigate the differences in language.

Kind regards,
Julie

Julie A. Breeden-Alemi, DVM

U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1
Breedon-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Ann Tillman [<mailto:Ann@PyxisRC.com>]
Sent: Tuesday, September 20, 2016 10:48 AM
To: Breedon-Alemi, Julie <Breedon-Alemi.Julie@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Julie,

My responses are noted below.

Ann

From: Breedon-Alemi, Julie [<mailto:Breedon-Alemi.Julie@epa.gov>]
Sent: September 20, 2016 10:03 AM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Hi Ann,

I am working on the label comments for both File Symbol 91300-A and –L. Can you please address the following two topics:

1. Can you explain again why the 91300-L label needs to have [tube][vial] options rather than choosing one to use consistently throughout the label? These products are currently going to be packaged in an applicator that is more like a “vial” but the client will want the option to amend their registrations to add a different CRP package that is a tube. In fact, if these products ever get registered, I will be submitting amendments to do just that.
2. The Side Effects text for both the cats (91300-A) and dogs (91300-L) differ quite a bit from the cited labels and text proposed in mitigation. Where is the text on the submitted labels coming from?

This is the text on the Frontline Plus labels.

SIDE EFFECTS: Cats may experience some temporary irritation at the site of application. If signs persist or become more severe within a few days of application, consult a veterinarian immediately.

This is the text in the Sept. 30, 2011 letter from Lois Rossi on label changes. Your label comments noted for me to add this sentence on these two labels: “In some cases, vomiting or diarrhea may result due to grooming after treatment.” I am perfectly willing to change the Side Effects to the same language as on the Frontline Plus labels.

EPA Response

EPA is requesting, via letter, that registrants make appropriate label changes for individual cat and dog spot-on products within 6 months of receipt. See also the response to Issue #4. Similar to FDA-approved drug labels, EPA is working to ensure product labels include information on side effects and possible adverse reactions, and instructions in case of an adverse reaction. For example, EPA proposes the following language under the heading, Side Effects: *"Monitor your cat/dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or [Registrant at 1-800-number]."*

Julie

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Monday, September 19, 2016 8:52 AM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Julie,

The revised data matrices and Certification for the dog product are attached.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: September 15, 2016 12:40 PM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: RE: EPA File Symbol 91300-L

Hi Ann,

I'll keep watch for the documents.

Julie

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Thursday, September 15, 2016 11:14 AM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Julie,

If acceptable to you, Promika will switch to cite-all for efficacy and CAC. I will send out the offers-to-pay and forward you a new Certification (8570-34) and updated data matrices.

Ann

From: Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]
Sent: September 15, 2016 10:14 AM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: FW: EPA File Symbol 91300-L

Good morning Ann,

Attached is the efficacy review for File Symbol 91300-L. Please let me know how you would like to proceed.

Thank you,
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Breeden-Alemi, Julie
Sent: Wednesday, September 14, 2016 10:54 AM
To: 'Ann Tillman' <Ann@PyxisRC.com>
Subject: RE: EPA File Symbol 91300-L

Hi Ann,

Attached are initial label comments for File Symbol 91300-L. I'll touch base with additional information regarding the reviews ASAP!

Please respond that you are aware that the Agency is issuing time-limited registrations for new pet spot-on products having an expiration date of two years from the time of registration. Quarterly enhanced incident reports and sales information will need to be submitted for all registered pet spot-on products. This would apply for File Symbols 91300-A and 91300-L.

Many thanks and enjoy your day!
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Ann Tillman [<mailto:Ann@PyxisRC.com>]
Sent: Wednesday, September 14, 2016 9:19 AM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Julie,

I was wondering if you were handling the Promika ZoGuard Plus for Dogs action, toq (91300-L). I just wondered if you will have label changes soon or if I should go ahead and make changes now based on your comments for the cat label.

Ann

Breeden-Alemi, Julie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Wednesday, September 21, 2016 11:28 AM *Re: ub*
To: Breeden-Alemi, Julie
Cc: Davis, Kable; IVB1
Subject: RE: Reg. No. 91300-L
Attachments: 20160921 91300-L 8570-27 p1.pdf; 20160921 91300-L 8570-27 p2.pdf

Julie,

Signed forms are attached.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: September 21, 2016 11:09 AM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: Reg. No. 91300-L

Good morning, Ann.

For File Symbol 91300-L, Promika ZoGuard Plus for Dogs, could you please send a revised Formulator's Exemption Statement to correspond with the revised CSF dated Feb. 22, 2016?

Thank you,
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Monday, February 22, 2016 10:05 AM *Re: ub*
To: Breeden, Julie <Breeden.Julie@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: Reg. No. 91300-L

Julie,

Please find the revised CSF for this product.

Ann

Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW

Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com

From: Breeden, Julie [<mailto:Breeden.Julie@epa.gov>]
Sent: February 18, 2016 4:18 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: Reg. No. 91300-L

Good afternoon Ann,

The action regarding File Symbol No. 91300-L is in progress. The Product Chemistry screen results noted deficiencies in the CSF regarding the calculations of the Nominal Concentrations for the AIs. Could you please review and revise these numbers as well as adjusting the amounts of the other ingredients accordingly? If you'd like to discuss specifics, I'm in the office today until 5:15pm. I am out of the office tomorrow, but will return Monday. Please try to send revisions within a week after which time we'll have to issue a 10-day letter.

Many thanks,
Julie

Julie A. Breeden, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden.Julie@epa.gov
Phone: 703.347.0511

Breeden-Alemi, Julie

From: Breeden-Alemi, Julie
Sent: Thursday, September 15, 2016 3:33 PM
To: 'Ann Tillman'
Subject: RE: File Symbol 91300-A and -1300-L CRP Certifications

Thanks, Ann. I'll get these to Lindsay today!
Julie

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Thursday, September 15, 2016 3:29 PM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: File Symbol 91300-A and -1300-L CRP Certifications

Julie,

I updated the CRP certifications. Let me know if Lindsey has any changes. Note that I added photos of the opening instructions to the certs since there are two different CRP packages.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: September 15, 2016 1:35 PM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: File Symbol 91300-A and -1300-L CRP
Importance: High

Hi Ann,

Are you available for a phone call today between 1:30pm and 2pm or at 4pm? Lindsay Roe and I would like to touch base regarding CRP. We called and were transferred to your VM, but there was so much beeping that we are not sure if it was recording or not recording. Thus... the email.
Thanks, Ann!

Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

Breeden-Alemi, Julie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Thursday, September 15, 2016 10:30 AM
To: Breeden-Alemi, Julie
Subject: RE: EPA File Symbol 91300-L
Attachments: 091300-xxxxx 20160915 Promika ZoGuard Plus Dogs Label.pdf; 091300-xxxxx 20160915 Promika ZoGuard Plus Dogs Label chgs.pdf

Julie,

See the changes made to the 91300-L label. I think the layout is clearer than it was on the original version. I forgot to respond that I am familiar with the conditions imposed on time-limited registrations for pet spot-on products.

Ann

From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: September 14, 2016 10:54 AM
To: Ann Tillman <Ann@PyxisRC.com>
Subject: RE: EPA File Symbol 91300-L

Hi Ann,

Attached are initial label comments for File Symbol 91300-L. I'll touch base with additional information regarding the reviews ASAP!

Please respond that you are aware that the Agency is issuing time-limited registrations for new pet spot-on products having an expiration date of two years from the time of registration. Quarterly enhanced incident reports and sales information will need to be submitted for all registered pet spot-on products. This would apply for File Symbols 91300-A and 91300-L.

Many thanks and enjoy your day!

Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Ann Tillman [mailto:Ann@PyxisRC.com]
Sent: Wednesday, September 14, 2016 9:19 AM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: EPA File Symbol 91300-L

Julie,

I was wondering if you were handling the Promika ZoGuard Plus for Dogs action, too (91300-L). I just wondered if you will have label changes soon or if I should go ahead and make changes now based on your comments for the cat label.

Breeden, Julie

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Monday, February 22, 2016 10:05 AM
To: Breeden, Julie
Cc: Davis, Kable; IVB1
Subject: RE: Reg. No. 91300-L
Attachments: 20160222 91300-L 8570-4.pdf

Resubmission

TO: ANN

FROM:

Julie,

Please find the revised CSF for this product.

Ann

*Ann M. Tillman, Ph.D.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
Office (253) 853-7369
Fax (253) 853-5516
Email Ann@PyxisRC.com*

From: Breeden, Julie [mailto:Breeden.Julie@epa.gov]
Sent: February 18, 2016 4:18 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: Reg. No. 91300-L

Good afternoon Ann,

The action regarding File Symbol No. 91300-L is in progress. The Product Chemistry screen results noted deficiencies in the CSF regarding the calculations of the Nominal Concentrations for the AIs. Could you please review and revise these numbers as well as adjusting the amounts of the other ingredients accordingly? If you'd like to discuss specifics, I'm in the office today until 5:15pm. I am out of the office tomorrow, but will return Monday. Please try to send revisions within a week after which time we'll have to issue a 10-day letter.

Many thanks,
Julie

Julie A. Breeden, DVM
U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1
Breeden.Julie@epa.gov
Phone: 703.347.0511



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Promika, LLC/91300	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Promika, LLC/Promika ZoGuard Plus for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Promika, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. CT NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-5 Product Name Frontline Plus for Dogs	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R315 (48: New end use product). The fee which has been paid is \$8,820.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify)	Bulk-HDPE or coated metal drums
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.023, 0.045, 0.091, 0.136 fl oz	No. per container 1, 3, 6	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container CRP 0.069, 0.135, 0.273, 0.408 fl oz/0.138, 0.27, 0.546, 0.816 fl oz; non-CRP 0.68 fl oz; bulk 55, 275 gal		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input checked="" type="checkbox"/> Other on box and insert		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Ann M. Tillman		Title Agent		Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Consultant			
4. Typed Name Ann M. Tillman		5. Date Dec. 14, 2015			

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PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

December 14, 2015 **MRID 49770000**

ELECTRONIC DELIVERY

Richard Gebken (PM 10)
Document Processing Desk (**REGFEE**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Promika, LLC
 Promika ZoGuard Plus for Dogs (EPA File Symbol 91300-)
 Application for New Pesticide Registration
 PRIA Category R315

Dear Mr. Gebken,

On behalf of Promika, LLC, we are submitting an application for registration of Promika ZoGuard Plus for Dogs, an end use product containing the active ingredients fipronil and (S)-methoprene. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Proposed labeling for Promika ZoGuard Plus for Dogs
4. Formulator's Exemption Statement, two (2) pages (EPA Form 8570-27)
5. Certification with Respect to Citation of Data (EPA Form 8570-34)
6. Agency Internal Use Copy of the Data Matrix (EPA Form 8570-35)
7. Public File Copy of the Data Matrix (EPA Form 8570-35)
8. Child Resistant Packaging Certification (two (2) pages)
9. Copy of PRIA payment
10. Three (3) Letters of Authorization from the sponsor of the CRP studies
11. Letter of Authorization from Promika, LLC
12. Product Specific Data:

MRID	Guideline	Report Title
49770001	830.1550, 830.1600, 830.1650, 830.1670, 830.1750, 830.1800	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Formulation Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Promika ZoGuard Plus for Dogs. <i>Contains Confidential Business Information.</i>

DOCUMENTUM 176

MRID	Guideline	Report Title
49770002	830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7100, 830.7300, 830.7520	Tillman, A. M. Group B Self-Certification of Physical/Chemical Properties of Promika ZoGuard Plus for Dogs.
49770003	870.1300	Tillman, A. M. Promika ZoGuard Plus for Dogs: Waiver Request for Acute Inhalation Toxicity Data.

The analytical method for this product is identical to the method submitted for Promika ZoGuard Plus for Cats (MRID 49769902).

The CRP data cited for this product on the data matrix are also listed in the enclosed letter of authorization. Two new studies were submitted under separate cover by the sponsor of the studies and MRIDs are not yet available. The data support a commercial package of one strip of 3 applicators, but since the data show high passes, Promika would like to market two strips of 3 applicators per carton as noted on the draft label. Promika believes that the previously submitted and approved CRP data can be bridged to support the additional retail package size (two strips of 3 applicators). An additional package size of 1 applicator per carton is supported by the new CRP studies.

Promika, LLC's Promika ZoGuard Plus for Dogs qualifies for formulator's exemption. This action falls under PRIA category R315 (48: New end use non-food product). The fee for this action is \$8,820 and has been paid.

Please contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures



Promika, LLC

Randall V Canady

1204 Village Market Place, #273

Morrisville, NC 27560

919-610-1065

Randy.Canady@PromikaLLC.com

November 26, 2014

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Ann Tillman, Mike Kellogg, Leanne Pruett, Janelle Kay, Maryanne Geisbush, Nicole Cochran, or Nicki Purnell of Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Promika, LLC. (EPA Company Number 91300), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Regards,

Chief Executive Officer
Promika, LLC

cc: Pyxis Regulatory Consulting, Inc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date September 16, 2016	EPA Reg. No./File Symbol 91300-L	Page 1 of 13
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	49770001	Promika, LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	49770001	Promika, LLC	OWN	
830.1620	Description of Production Process				Not Required ¹
830.1650	Description of Formulation Process	49770001	Promika, LLC	OWN	
830.1670	Discussion of Formation of Impurities	49770001	Promika, LLC	OWN	
830.1700	Preliminary Analysis				Not required ¹
830.1750	Certified Limits	49770001	Promika, LLC	OWN	
830.1800	Enforcement Analytical Method	49769902	Promika, LLC	OWN	See Endnote ²
830.6302	Color	49770002	Promika, LLC	OWN	
830.6303	Physical State	49770002	Promika, LLC	OWN	
830.6304	Odor	49770002	Promika, LLC	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not required ¹
830.6314	Oxidation/Reduction: Chemical Incompatibility	49770002	Promika, LLC	OWN	Waiver ³
830.6315	Flammability	49770002	Promika, LLC	OWN	
830.6316	Explosibility	49770002	Promika, LLC	OWN	Waiver ⁴

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage Stability	49770002	Promika, LLC	OWN	PRN 92-5 ⁵
830.6319	Miscibility				Not Applicable ⁶
830.6320	Corrosion Characteristics	49770002	Promika, LLC	OWN	PRN 92-5 ⁴
830.6321	Dielectric Breakdown Voltage				Not Applicable ⁵
830.7000	pH	49770002	Promika, LLC	OWN	
830.7050	UV/Visible Absorption				Not Required ¹
830.7100	Viscosity	49770002	Promika, LLC	OWN	
830.7200	Melting Point/Melting Range				Not Required ¹
830.7220	Boiling Point/Boiling Range				Not Required ¹
830.7300	Density/Relative Density/Bulk Density	49770002	Promika, LLC	OWN	
830.7370	Dissociation Constants in Water				Not Required ¹
830.7520	Particle Size, Fiber Length, and Diameter Distribution			OWN	Waiver ⁵
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not Required ¹
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not Required ¹
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not Required ¹
870.1100	Acute Oral Toxicity: Rat	44942004		OLD	
870.1200	Acute Dermal Toxicity: Rat	44942005		OLD	
870.1300	Acute Inhalation Toxicity: Rat	49770003	Promika, LLC	OWN	Waiver
870.2400	Primary Eye Irritation: Rabbit	44942006		OLD	
870.2500	Primary Dermal Irritation	44942007		OLD	
870.2600	Dermal Sensitization	44942008		OLD	
870.7200	Companion Animal Safety	Cite-All		PAY	
810.3300	Product Performance	Cite-All		PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
US 16 CFR § 1700	Child Resistant Packaging Study	48703501	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48703502	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48703503	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48703504	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48652701	Horizon Valley Generics, Inc.	PER	
		49179701	TruProdigy	PER	
		49179702	TruProdigy	PER	
		49179703	TruProdigy	PER	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
US 16 CFR § 1700	Child Resistant Packaging Study – Single Applicator	KVS/201522	Klocke Verpackungs-Service	PER	
		KVS/201521	Klocke Verpackungs-Service	PER	
		49649301	Klocke Verpackungs-Service	PER	
		49649302	Klocke Verpackungs-Service	PER	
		49649303	Klocke Verpackungs-Service	PER	
		49649304	Klocke Verpackungs-Service	PER	
		49649305	Klocke Verpackungs-Service	PER	
		49649306	Klocke Verpackungs-Service	PER	
		49649307	Klocke Verpackungs-Service	PER	
		49649308	Klocke Verpackungs-Service	PER	
		49649309	Klocke Verpackungs-Service	PER	
		49649310	Klocke Verpackungs-Service	PER	
		49681401	Klocke Verpackungs-Service	PER	
		49681402	Klocke Verpackungs-Service	PER	
		49719401	Klocke Verpackungs-Service	PER	
		49719402	Klocke Verpackungs-Service	PER	

Product-Specific Data Requirements

Promika, LLC will make offers-to-pay to the following companies on the Fipronil and S-methoprene data submitters list of June 30, 3016.

	Cite-All	Syngenta Crop Protection, LLC	PAY	
	Cite-All	The Scotts Company	PAY	
	Cite-All	Bayer Cropscience LP	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Bayer Environmental Science	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	Zoetis, Inc.	PAY	
		Cite-All	McLaughlin Gormley King Co.	PAY	
		Cite-All	Virbac AH, Inc.	PAY	
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Vetoquinol USA	PAY	
		Cite-All	Reckitt Benckiser LLC	PAY	
		Cite-All	Cheminova A/S	PAY	
		Cite-All	J. J. Mauget Co.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	Chemsico	PAY	
		Cite-All	Sumitomo Chemical Co., Ltd.	PAY	
		Cite-All	Adama Makhteshim Ltd.	PAY	
		Cite-All	Gharda Chemicals Ltd.	PAY	
		Cite-All	Finchimica S.p.A.	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Control Solutions, Inc.	PAY	
		Cite-All	Virbac	PAY	
		Cite-All	Combat Insect Control Systems	PAY	
		Cite-All	Pyrethroid Working Group	PAY	
		Cite-All	Merial, Inc.	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Cheminova Inc.	PAY	
		Cite-All	Elanco US Inc.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Innovative Pest Control Products	PAY	
		Cite-All	FIFRA Endangered Species Task Force	PAY	
		Cite-All	Adama Irvita N.V.	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Klocke Verpackungs-Service Gmbh	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agricultural Handler Exposure Task Force	PAY	
		Cite-All	Ceva Animal Health LLC	PAY	
		Cite-All	Sharda USA LLC	PAY	
		Cite-All	Gharda Generics, Inc.	PAY	
		Cite-All	Fidopharm, Inc.	PAY	
		Cite-All	Norbrook Laboratories Limited	PAY	
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Linouvel, Inc.	PAY	
		Cite-All	Zhejiang Hisun Pharmaceuticals Co., Ltd.	PAY	
		Cite-All	Argite LLC	PAY	
		Cite-All	Argite – Fipronil LLC	PAY	
		Cite-All	Fipronex Solutions Inc.	PAY	
		Cite-All	Virbac S.A.	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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DATA MATRIX

Date September 16, 2016	EPA Reg. No./File Symbol 91300-L	Page 9 of 13
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Raymat Materials, Inc.	PAY	
		Cite-All	Chanelle Pharmaceuticals Manufacturing	PAY	
		Cite-All	Horizon Valley Generics, Inc.	PAY	
		Cite-All	American Vet Sciences LLC	PAY	
		Cite-All	Prodigy Technical Holding, LLC	PAY	
		Cite-All	Tru Prodigy	PAY	
		Cite-All	TruRx LLC	PAY	
		Cite-All	Adela Monica Buljubasich	PAY	
		Cite-All	2 Star Solution Inc.	PAY	
		Cite-All	Fipronil Task Force LLC Pet Cluster	PAY	
		Cite-All	Fipronil Task Force LLC Non-crop Cluster	PAY	
		Cite-All	Fipronil Task Force LLC Crop Cluster	PAY	
		Cite-All	CAP Supply, Inc.	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date September 16, 2016	EPA Reg. No./File Symbol 91300-L	Page 10 of 13
Applicant's/Registrant's Name & Address Promikā, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Shanghai Neway Animal Health Co., Ltd.	PAY	
		Cite-All	TG Medwise, Ltd.	PAY	
		Cite-All	Tigris Environmental Science LLC	PAY	
		Cite-All	The Scotts Company	PAY	
		Cite-All	ADM Animal Nutrition	PAY	
		Cite-All	Sergeant's Pet Care Products, Inc.	PAY	
		Cite-All	The Hartz Mountain Corp.	PAY	
		Cite-All	Wellmark International	PAY	
		Cite-All	S. C. Johnson & Son Inc.	PAY	
		Cite-All	Nippon Soda Co., Ltd.	PAY	
		Cite-All	Clarke Mosquito Control Products Inc.	PAY	
		Cite-All	Chattem, Inc.	PAY	
		Cite-All	Zep Commercial Sales & Service	PAY	
		Cite-All	Control Solutions, Inc.	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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DATA MATRIX

Date September 16, 2016	EPA Reg. No./File Symbol 91300-L	Page 11 of 13
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Management Contract Services Inc.	PAY	
		Cite-All	Merial, Inc.	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	B2E Corp.	PAY	
		Cite-All	Babolna Bioenvironmental Centre Ltd.	PAY	
		Cite-All	Egis Pharmaceuticals Public Limited Co.	PAY	
		Cite-All	Valent Biosciences Corp.	PAY	
		Cite-All	Ambrands	PAY	
		Cite-All	Hartz-B2E LLC	PAY	
		Cite-All	Klocke Verpackungs-Service Gmbh	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	B2E Biotech LLC	PAY	
		Cite-All	Zocor Inc.	PAY	
		Cite-All	Ceva Animal Health LLC	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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DATA MATRIX

Date September 16, 2016	EPA Reg. No./File Symbol 91300-L	Page 12 of 13
Applicant's/Registrant's Name & Address Promika, LLC 501 Cascade Pointe Lane, Suite 102 Cary, NC 27513	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Fidopharm, Inc.	PAY	
		Cite-All	Loradochem, Inc.	PAY	
		Cite-All	Linouvel, Inc.	PAY	
		Cite-All	Envincio LLC	PAY	
		Cite-All	Raymat Materials Inc.	PAY	
		Cite-All	U.S. Animal Health	PAY	
		Cite-All	Horizon Valley Generics Inc.	PAY	
		Cite-All	Sequent Scientific Limited	PAY	
		Cite-All	Central Garden & Pet Co.	PAY	
		Cite-All	CAP Supply Inc.	PAY	
		Cite-All	Shanghai New Animal Health Co., Ltd.	PAY	
Generic Data Requirements					
Promika LLC's Promika ZoGuard Plus for Dogs qualifies for Formulator's Exemption for fipronil and S-methoprene generic data requirements.					

Signature 	Name and Title Ann M. Tillman, Consultant	Date Sept. 16, 2016
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Endnotes for Data Matrix for Promika ZoGuard Plus for Dogs

- ¹ **830.1650** - These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- ² **830.1800** – This report was submitted concurrent with the application for registration of Promika ZoGuard Plus for Cats.
- ³ **830.6314** – Promika, LLC requests a waiver from the requirement of this data requirement because this product is intended for use as an on-animal spot-on. During normal usage, it will not come into contact with any oxidizing or reducing agents. This product does not contain any oxidizing or reducing agents. Please refer to the Confidential Statement of Formula for Promika ZoGuard Plus for Dogs.
- ⁴ **830.6316** – Promika LLC requests a waiver from this data requirement because fipronil and (S)-methoprene do not have the chemical bonds or functional groups associated with explosive chemicals. There are no potentially explosive ingredients in Promika ZoGuard Plus for Dogs (refer to the CSF for Promika ZoGuard Plus for Dogs).
- ⁵ **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Promika, LLC agrees to conduct this study as a condition of registration.
- ⁶ **830.6319, 830.6321, 830.7520** – Promika ZoGuard Plus for Dogs is not an emulsifiable concentrate and its labeling does not allow it to be diluted with petroleum solvents; therefore miscibility data is not applicable to Promika ZoGuard Plus for Dogs. Promika ZoGuard Plus for Dogs is not to be applied around electrical equipment; therefore dielectric breakdown voltage data is not applicable. Promika, LLC requests a waiver from the requirement of particle size, fiber length, and diameter distribution because the product is not a fibrous material and is not a water-insoluble material.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Revised

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Promika LLC c/o Pyxis Regulatory Consulting 4110 136th St. CT NW Gig Harbor, WA, 253-8537369	EPA Registration Number/File Symbol 91300
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-Methoprene	Date Sept. 19, 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor nonfood	Product Name Promika ZoGuard Plus for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

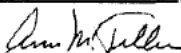
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature  Digitally signed by Ann M. Tillman DN: cn=Ann M. Tillman, o=Pyxis Regulatory Consulting, Inc., ou=Pyxis, email=Ann@PyxisRC.com, c=US Date: 2016.09.19 08:43:04 -04'00'	Date Sept. 19, 2016	Typed or Printed Name and Title Ann M. Tillman, Agent
---	------------------------	--



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address Promika, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. CT NW Gig Harbor, WA 98332	EPA File Symbol/Registration Number 91300-L
	Product Name Promika ZoGuard Plus for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) 02/22/2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fipronil
 (S)-methoprene

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
(S)-methoprene	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
Digitally signed by Ann M. Tillman DN: cn=Ann M. Tillman, o=Pyxis Regulatory Consulting, Inc., ou=Pyxis, email=Ann@PyxisRC.com, c=US Date: 2016.09.21 11:25:37 -0400 Signature	Name and Title Ann M. Tillman, Agent	Date 09/21/2016

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy

Product Source Information May be Entitled to Confidential Treatment

Formulator's Exemption Statement (40 CFR 152.85)

Applicant's Name and Address Promika, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. CT NW Gig Harbor, WA 98332	EPA File Symbol/Registration Number 91300-L
	Product Name Promika ZoGuard Plus for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) 02/22/2016

Fipronil
(S)-methoprene

(4) The following active ingredients in this product qualify for the formulator's exemption.

[illegible]

21-Day Screen Completed by
Contractor

21-Day Expires on 1-5-16

Jacket # 91300-L

MRID# 497700

Content Screen: Recommend to ☒ **Pass** / Fail

11-3 Review: ☒ **Pass** / Fail / NA

Overall Status: Recommend to ☒ **Pass** / Fail

Transfer This Jacket to:

STEPHEN SCHAEFER

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12-15-15

Experts In-Processing Signature: B.B. Date 12-18-15 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>91300-L</u>		EPA Receipt Date: <u>12-15-15</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (<u>Electronic labels on CD</u> are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	<u>Notice of Filing</u> included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Documentation: (PASS)

- All required forms are complete.

Inerts: (PASS)

- Inerts approved for non-food use.

II-3: (PASS)

- MPID 497700

Status: (PASS)

MS 12/30/15

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 17, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-512125
EPA File Symbol or Registration Number: 91300-L
Product Name: PROMIKA ZOGUARD PLUS FOR DOGS
EPA Receipt Date: 15-Dec-2015
EPA Company Number: 91300
Company Name: PROMIKA, LLC

ANN TILLMAN
PYXIS REGULATORY CONSULTING, INC.
AGENT FOR: PROMIKA, LLC
4110 136TH ST. N.W.
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R315

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY::PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{978642;~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S- 978642

EPA File Symbol/Reg. No.

91300-L

Pin-Punch Date:

12/15/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested: 2315

Granted: 2315

Amount Due: \$ 8820

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: L Patel

Date: 12/17/15

Remarks:

DOCUMENTUM

Ann Tillman

From: notification@pay.gov
Sent: December 02, 2015 10:08 AM
To: Brooke Hedrick
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25OMNTVN
Agency Tracking ID: 74917369564
Transaction Type: Sale
Transaction Date: 12/02/2015 10:07:36 AM EST

Account Holder Name: Brooke Hedrick

Transaction Amount: \$8,820.00
Card Type: Visa
Card Number: *****4032

Registration Number:
Company Name: Promika, LLC
Company Number: 91300
Action Code: R315

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WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Promika LLC c/o Pyxis Regulatory Consulting 4110 136th St. CT NW Gig Harbor, WA, 253-8537369	EPA Registration Number/File Symbol 91300
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-Methoprene	Date Dec. 14, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor nonfood	Product Name Promika ZoGuard Plus for Dogs

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Digitally signed by Ann M. Tillman
 DN: cn=Ann M. Tillman, o=Pyxis
 Regulatory Consulting, Inc., ou=Pyxis,
 email=Ann@PyxisRC.com, c=US
 Date: 2015.12.01 10:20:21 -05'00'

Date

Dec. 14, 2015

Typed or Printed Name and Title

Ann M. Tillman, Agent



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address Promika, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. CT NW Gig Harbor, WA 98332	EPA File Symbol/Registration Number 91300-xx
	Product Name Promika ZoGuard Plus for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) 11/20/2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Fipronil
 (S)-methoprene

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).


- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
(S)-methoprene	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
Signature 	Name and Title Ann M. Tillman, Agent	Date 12/02/2015

Digitally signed by Ann M. Tillman
 DN: cn=Ann M. Tillman,
 o=Pyxis Regulatory
 Consulting, Inc., ou=Pyxis
 Consulting, Inc., email=Ann@PyxisRC.com,
 c=US
 Date: 2015.12.01 09:41:04
 +05'00'

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy

*Product Source Information May be
 Entitled to Confidential Treatment*

DOCUMENTUM



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address Promika, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. CT NW Gig Harbor, WA 98332	EPA File Symbol/Registration Number 91300-xx
	Product Name Promika ZoGuard Plus for Dogs
	Date of Confidential Statement of Formula (EPA Form 8570-4) 11/20/2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):



Fipronil
(S)-methoprene

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).
- OR**
- ☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil		
Digitally signed by Ann M. Tillman DN: cn=Ann M. Tillman, o=Pyxis Regulatory Consulting, Inc., ou=Pyxis email=Ann@PyxisRC.com, c=US Date: 2015.12.01 09:38:07 -05'00'	Name and Title Ann M. Tillman, Agent	Date 12/02/2015

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy

*Product Source Information May be Entitled to
 Confidential Treatment*

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DATA MATRIX

Date December 10, 2015	EPA Reg. No./File Symbol 91300-	Page 1 of 7
Applicant's/Registrant's Name & Address Promika, LLC 1204 Village Market Place, #273 Morrisville, NC 27560	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	49770001	Promika, LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	49770001	Promika, LLC	OWN	
830.1620	Description of Production Process				Not Required ¹
830.1650	Description of Formulation Process	49770001	Promika, LLC	OWN	
830.1670	Discussion of Formation of Impurities	49770001	Promika, LLC	OWN	
830.1700	Preliminary Analysis				Not required ¹
830.1750	Certified Limits	49770001	Promika, LLC	OWN	
830.1800	Enforcement Analytical Method	49769902	Promika, LLC	OWN	See Endnote ²
830.6302	Color	49770002	Promika, LLC	OWN	
830.6303	Physical State	49770002	Promika, LLC	OWN	
830.6304	Odor	49770002	Promika, LLC	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not required ¹
830.6314	Oxidation/Reduction: Chemical Incompatibility	49770002	Promika, LLC	OWN	Waiver ³
830.6315	Flammability	49770002	Promika, LLC	OWN	
830.6316	Explosibility	49770002	Promika, LLC	OWN	Waiver ⁴

Signature 	Name and Title Ann M. Tillman, Consultant	Date Dec. 10, 2015
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DATA MATRIX

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Applicant's/Registrant's Name & Address Promika, LLC 1204 Village Market Place, #273 Morrisville, NC 27560	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage Stability	49770002	Promika, LLC	OWN	PRN 92-5 ⁵
830.6319	Miscibility				Not Applicable ⁶
830.6320	Corrosion Characteristics	49770002	Promika, LLC	OWN	PRN 92-5 ⁴
830.6321	Dielectric Breakdown Voltage				Not Applicable ⁵
830.7000	pH	49770002	Promika, LLC	OWN	
830.7050	UV/Visible Absorption				Not Required ¹
830.7100	Viscosity	49770002	Promika, LLC	OWN	
830.7200	Melting Point/Melting Range				Not Required ¹
830.7220	Boiling Point/Boiling Range				Not Required ¹
830.7300	Density/Relative Density/Bulk Density	49770002	Promika, LLC	OWN	
830.7370	Dissociation Constants in Water				Not Required ¹
830.7520	Particle Size, Fiber Length, and Diameter Distribution			OWN	Waiver ⁵
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not Required ¹
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550

Signature 	Name and Title Ann M. Tillman, Consultant	Date Dec. 10, 2015
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Applicant's/Registrant's Name & Address Promika, LLC 1204 Village Market Place, #273 Morrisville, NC 27560		Product Promika ZoGuard Plus for Dogs			
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not Required ¹
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not Required ¹
870.1100	Acute Oral Toxicity: Rat	44942004		OLD	
870.1200	Acute Dermal Toxicity: Rat	44942005		OLD	
870.1300	Acute Inhalation Toxicity: Rat	49770003	Promika, LLC	OWN	Waiver
870.2400	Primary Eye Irritation: Rabbit	44942006		OLD	
870.2500	Primary Dermal Irritation	44942007		OLD	
870.2600	Dermal Sensitization	44942008		OLD	
870.7200	Companion Animal Safety	44942104 45143901 45612702 ✓ 45620507	Merial, Inc. Merial, Inc.	OLD OLD PAY PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Dec. 10, 2015
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Applicant's/Registrant's Name & Address Promika, LLC 1204 Village Market Place, #273 Morrisville, NC 27560	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300 ✓	Product Performance ✓	✓ 43121114 ✓		OLD	
		✓ 43121115 ✓		OLD	
		43577712 ✓		OLD	
		✓ 43121116 ✓		OLD	
		✓ 43121117 ✓		OLD	
		✓ 43121118 ✓	- EUP	OLD	
		✓ 43121122 ✓	- EUP	OLD	
		✓ 44942105 ✓		OLD	
		✓ 44942106 ✓		OLD	
		45612701 ✓	Merial, Inc.	PAY	
		✓ 45620501 ✓	Merial, Inc.	PAY	
		2002 ✓ 45620502 ✓	Merial, Inc.	PAY	
		2002 ✓ 45620503 ✓	Merial, Inc.	PAY	
		✓ 45620504 ✓	Merial, Inc.	PAY	
		✓ 45620505 ✓	Merial, Inc.	PAY	
		✓ 45620506 ✓	Merial, Inc.	PAY	
		✓ 45866902 ✓	Merial, Inc. Query	PAY	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Dec. 10, 2015
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Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
US 16 CFR § 1700	Child Resistant Packaging Study	48703501	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48703502	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48703503	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48703504	Chanelle Pharmaceuticals Manufacturing, Ltd.	PER	
		48652701	Horizon Valley Generics, Inc.	PER	
		49179701	TruProdigy	PER	
		49179702	TruProdigy	PER	
		49179703	TruProdigy	PER	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Dec. 10, 2015
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DATA MATRIX

Date December 10, 2015	EPA Reg. No./File Symbol 91300-	Page 6 of 7
Applicant's/Registrant's Name & Address Promika, LLC 1204 Village Market Place, #273 Morrisville, NC 27560	Product Promika ZoGuard Plus for Dogs	
Ingredient Fipronil (CAS No. 120068-37-3), (S)-methoprene (CAS No. 65733-16-6)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
US 16 CFR § 1700	Child Resistant Packaging Study – Single Applicator	KVS/201522	Klocke Verpackungs-Service	PER	
		KVS/201521	Klocke Verpackungs-Service	PER	
		49649301	Klocke Verpackungs-Service	PER	
		49649302	Klocke Verpackungs-Service	PER	
		49649303	Klocke Verpackungs-Service	PER	
		49649304	Klocke Verpackungs-Service	PER	
		49649305	Klocke Verpackungs-Service	PER	
		49649306	Klocke Verpackungs-Service	PER	
		49649307	Klocke Verpackungs-Service	PER	
		49649308	Klocke Verpackungs-Service	PER	
		49649309	Klocke Verpackungs-Service	PER	
		49649310	Klocke Verpackungs-Service	PER	
		49681401	Klocke Verpackungs-Service	PER	
		49681402	Klocke Verpackungs-Service	PER	
		49719401	Klocke Verpackungs-Service	PER	
		49719402	Klocke Verpackungs-Service	PER	
Generic Data Requirements					
Promika LLC's Promika ZoGuard Plus for Dogs qualifies for Formulator's Exemption for fipronil and S-methoprene generic data requirements.					

Signature 	Name and Title Ann M. Tillman, Consultant	Date Dec. 10, 2015
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Endnotes for Data Matrix for Promika ZoGuard Plus for Dogs

-
- ¹ **830.1650** - These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- ² **830.1800** - This report was submitted concurrent with the application for registration of Promika ZoGuard Plus for Cats.
- ³ **830.6314** - Promika, LLC requests a waiver from the requirement of this data requirement because product is intended for use as an on-animal spot-on. During normal usage, it will not come into contact with any oxidizing or reducing agents. This product does not contain any oxidizing or reducing agents. Please refer to the Confidential Statement of Formula for Promika ZoGuard Plus for Dogs.
- ⁴ **830.6316** - Promika LLC requests a waiver from this data requirement because fipronil and (S)-methoprene do not have the chemical bonds or functional groups associated with explosive chemicals. There are no potentially explosive ingredients in Promika ZoGuard Plus for Dogs (refer to the CSF for Promika ZoGuard Plus for Dogs).
- ⁵ **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Promika, LLC agrees to conduct this study as a condition of registration.
- ⁶ **830.6319, 830.6321, 830.7520** - Promika ZoGuard Plus for Dogs is not an emulsifiable concentrate and its labeling does not allow it to be diluted with petroleum solvents; therefore miscibility data is not applicable to Promika ZoGuard Plus for Dogs. Promika ZoGuard Plus for Dogs is not to be applied around electrical equipment; therefore dielectric breakdown voltage data is not applicable. Promika, LLC requests a waiver from the requirement of particle size, fiber length, and diameter distribution because the product is not a fibrous material and is not a water-insoluble material.

